House of Commons Standing Committee on Health Canada
Drug Shortages
Overview of Health Canada Drug Shortages Activities

CONTEXT:

In September 2010, the Canadian Pharmacists Association (CPhA) conducted a survey of their membership to gather information on the extent, causes and impacts of drug shortages in Canada. The final survey report was released in December 2010, and received significant media attention. The report highlights the complexity of the issue and provides recommendations on potential ways to alleviate the impacts of drug shortages. The CPhA requested a study of drug shortages by the Standing Committee on Health.

REASONS FOR SHORTAGES:

The supply chain for therapeutic products is very complex and supply interruptions are not uncommon. There are two broad triggers for a drug shortage.

1. Change in supply or demand that depletes or reduces supplies.

   Examples include: natural disasters, accidental product loss, manufacturing break-downs, shortage of raw material, and unanticipated changes in product demand.

2. Change in the product status, as a result of a regulatory reassessment of the risks and benefits, which leads to a product not being sold on the market. In this case, the shortage typically exists because product is considered not suitable for market, not because there are no supplies.

   Examples include: new submission, lot failure or specification deviations, GMP failure, or health hazard evaluation resulting in a product recall.

ROLES AND RESPONSIBILITIES

Access to therapeutic products involves industry, government (provincial and federal), health professionals and patients. There are no regulatory requirements for any of those involved with regard to shortage prevention, communication or management.

1) INDUSTRY

Drugs are manufactured and supplied by industry. As such, it is accepted that manufacturers and distributors should be responsible for understanding the supply needs for their product on the market, for assessing the potential impact of supply interruptions, and for managing drug supplies.

As a good public health practice, there is also an expectation that manufacturers will take steps to prevent supply chain interruptions for medically necessary products, or when interruptions are anticipated, to implement strategies to minimize the impact of supply

interruptions on patients. These include: monitoring supplies; rationing existing supplies; and when necessary, filing the appropriate submissions with the Health Canada to ensure continuity of supply on the market.

Finally, as the only participant who can provide accurate information on existing inventories or new supplies, it is also generally accepted that manufacturers should be responsible for communicating information regarding drug shortages to their customers.

2) Health Canada

Health Canada, as a Department, has a broad mandate to help Canadians maintain and improve their health, while respecting individual choices and circumstances. The Health Products and Food Branch, as a regulatory branch, is responsible for providing oversight to the sale of health products in Canada through the administration of the Food and Drugs Act. This includes:

- risk/benefit assessments to ensure that products sold on the Canadian market meet high standards with respect to safety, efficacy and quality; and
- associated communication activities, which promote the safe use of health products, enable informed decision-making, and ensure transparency and accountability within the regulatory system.

Health Canada has no authority to require a manufacturer to bring a product to the Canadian market or to maintain adequate supplies on the market to meet to the needs of patients. As mentioned, these are considered supply issues, and are the responsibility of industry.

There are a number of discretionary tools that the Department can use to prevent or minimize the impact of a shortage of medically necessary products, without compromising our role as a regulator. These include:

- expediting review of new submissions to authorize manufacturing changes, a new manufacturing facility or an alternate source of product;
- reviewing the potential impact of a shortage, as part of the benefit/risk assessment that is conducted when considering regulatory actions against a marketed product, or when considering enforcement action for manufacturing problems;
- providing technical advice and guidance to a manufacturer to facilitate receipt of a submission; and
- providing access to alternatives on an emergency basis through Health Canada's Special Access Programme (SAP).

Policy activities

In response to the recent reports of drug shortages, the Department initiated policy work to better understand the causes and impacts of drug shortages, and explore its role in monitoring or responding shortages in our capacity as a regulator.

In October 2010, the Department initiated a series of Technical Discussions to discuss proposals to modernize the regulatory system for therapeutic products. The sessions brought together stakeholders from industry, health professional, academic, patient and consumer groups, and covered a broad range of topics within the regulatory process.

A discussion paper on access issues related to drug shortages and discontinuations was presented and discussed at the October session. The paper outlined a model to support mandatory notification of drug shortages. An analysis of the feedback from this proposal is currently being undertaken.

On March 15, 2011, the Minister of Health sent a letter to Canada's Research Based Pharmaceutical Companies (Rx&D), the Canadian Generic Pharmaceutical Association (CGPA), and BIOTECanada requesting that association members voluntarily provide information on drug shortages based upon a set of criteria to be established by key stakeholders. The letter indicates that if this option is not viable, the Department will consider regulatory alternatives.

Drug Shortages

Government Commitments:	• Mr. Colin Carrie Parliamentary Secretary to the Minister of Health, CPC in response to Lib MP Hedy Fry stated "our Government recognizes the importance of affordable access to drugs as part of a quality health care system, and we work with the provinces and territories, who are responsible, by the way, for deciding which drugs are publicly covered. That is why we have consistently increased transfers to the provinces and territories by over 30% since we formed government, so they can continue to meet the health care needs of their residents." (Hansard June 2001)
Election Platform:	**NDP** (includeing positions on related issues that would impact Drug supply) • Reduce prescription drug costs with a national bulk-buying program (The Canadian Pharmacists Association has indicated that such a program would impact pharmaceutical supply and could lead to a shortage situation). • Phase in a pharma-care program, starting with low-income Canadians and those facing massive drug costs. • Called for a National Drug Strategy (which may include a National Drug Registry) • Moving towards more publicly funded research and development, driven by public priorities. **LIB** (includeing positions on related issues that would impact Drug supply) • Better Coverage of Prescription Drugs • Commitment to work with the provinces and territories to ensure that all Canadians from coast-to-coast-to-coast have a drug plan that covers the cost of prescription drugs for illnesses such as cancer, diabetes or arthritis that can be financially catastrophic to families.
SFT:	• The SFT called for the Government to invest in our system of universal health care. • The SFT also committed to renew the Health Accord which called for reasonable access to catastrophic drug coverage and a committed to expanded and accelerated collaboration in pharmaceuticals management, on a variety of fronts.
Budget:	• There are no direct references in the Budget to drug shortages however, the 2011 Budget included a commitment to research $15 million per year to CIHR to support advanced health-related research.

Liberal Statements:

- **Liberal Critic for Health, Dr. Hedy Fry** In June 2011 criticised the Government for a "failure to establish a national pharmaceutical strategy, which is a key goal of the 2004 health accord. Yet the budget makes no mention of this critical program ... [and asked] Will the minister stop passing the buck to the provinces and tell this house what her government will do to establish a pharmaceutical strategy? (Hedy Fry's Website)
- **Dr. Fry** stated that "Drug shortages became apparent across Canada in the last year and a half with muted response from the Conservative government, . . . Managing a serious challenge before it becomes a crisis is not only good stewardship - it's common sense. It is imperative that Parliament look into this matter as soon as possible, which is why I will be asking the Health Committee to examine drug shortages as its first study when Parliament resumes. By bringing in key researchers, industry, and physicians we can develop short-term recommendations as well as bring forward long-term solutions to address this problem.." (Hedy Fry's Website)
- **Judy M Foote Liberal MP (Random-Burin-St. George's)** noted that "the Conservatives failed to address the prescription supply needs then and they are failing now. A recent survey of pharmacists found that over 90 percent of pharmacists face drug shortages each week when filling prescriptions and a similar number noted that these shortages have gotten worse over the past year. Canadians are tired of waiting on the Conservative Government to act. The Liberal Party will be calling for the Standing Committee on Health to examine drug shortages as its first study this fall," (Judy M Foote's Website)

CPC:

- As part of the recent **Conservative Party Convention** the party considered the following resolution that "The Conservative Party believes all Canadians should have reasonable access to timely, quality health care services, regardless of their ability to pay. [and} iv) The government should work with the provinces and territories and professional medical groups to increase the supply of health care professionals where shortages exist. " (Conservative Party Convention Webpage)
- In March the **Minister of Health** sent a letter to drug manufacturers asking them to voluntarily submit information on shortages, and suggests that if they do not submit such information voluntarily, Health Canada will consider a regulatory option. (Ministerial Letter March 11, 2011)

NDP:

- **Hon. Jack Layton (Toronto—Danforth, NDP)**: In February Jack Layton posed the following question in the house ", throughout the country, pharmacists are finding it more and more difficult to obtain medications like penicillin and tetracycline. The situation is very serious and worse than ever. This shortage is making doctors' and pharmacists' jobs more difficult, and patients are worried. The budget must include solutions to this problem. Will the budget take into account the need to end this shortage of drugs?" (Hansard)

11-109054-225

Health Canada / Santé Canada

Drug Shortages - Update

12 May 2011

Canada

Previous Commitments

- On January 20th, 2011, the department outlined for the Minister three tasks it would undertake to fill information gaps on shortages.
  1. Continue informal information gathering to better determine the potential impacts of shortages on patients and health professionals and to discuss opportunities to improve the management of drug shortages.
  2. Ask CADTH to conduct an Environmental Scan with a focus on identifying underlying causes of shortages.
  3. Set up a contract with SECOR to analyze the pharmaceutical supply chain.
- On March 11, 2011, the Minister sent a letter to industry associations requesting that they voluntarily disclose information on shortages. The letter noted that in the event this option was not viable, Health Canada would examine regulatory alternatives.

Informal Information Gathering

What was already known

- Recent shortages in Canada were primarily in the generics market and associated with manufacturing delays and product discontinuation.
- Information from the US indicated that manufacturing delays and supply/demand issues were the most common reasons for shortages; however, nearly 50% of investigated shortages were of unknown cause.

What is known now

- Through conversations with industry, industry consultants, pharmacists, physicians, and drug plan managers, further understanding includes:
  - Shortages have decreased somewhat since the release of the CPhA report;
  - Antibiotics (66%) and antidepressants (33%) were the most commonly reported drugs in shortage;
  - According to the CMA, consequences of shortages could include: delayed access, increased coordination between physician and pharmacist, increased cost to patient (or non-adherence due to cost); and,
  - Despite considerable research internationally, the causes of many drug shortages are still unknown.

CADTH Environmental Scan

Report

- CADTH completed this report in late March and posted an abridged version on their website in mid-April

Findings

- Assesses international trends, noting that shortages are reported primarily in the US and UK; Australia, New Zealand, and Europe report few shortages
- Identifies information challenges in the system (overseas manufacturers, limited knowledge of Canadian license holders)
- Acknowledges that no organization is currently responsible for the collection and provision of information regarding drug shortages
- Notes that there is limited Canadian evidence from which to determine the prevalence or cause(s) of drug shortages
- Calls for further analysis of firms and actors in the Canadian drug supply chain

Supply Chain Analysis

- In March, upon completion of the CADTH environmental scan, the Department contacted SECOR Group to discuss a contract on drug shortages.
- The initial feedback indicated that an investigation into the causes and impacts of drug shortages are unlikely to yield more definitive informative than is currently available.
- Subsequent discussions have suggested a detailed analysis of the pharmaceutical supply chain may provide a better understanding of the Canadian supply situation and identify vulnerabilities in the supply chain.
- The Department is currently waiting to receive a draft proposal for consideration with projected costs and timelines.

Industry Leadership

Minister's Letter

- In March, the Minister sent a letter to Rx&D, BIOTECanada, and CGPA requesting that they voluntarily provide information on drug shortages.
- The letter asked that a set of criteria be established by key stakeholders.
- In the event that option was not viable, the Minister identified that the department would consider regulatory alternatives.

Response

- On May 10, 2011, the Minister received a letter from CGPA indicating that they had held a meeting on April 18 with other stakeholders to discuss how drug shortage information can be shared.
- Rx&D, BioteCanada, CPhA, CMA, the Canadian Society of Hospital Pharmacists, Canadian Association of Pharmacy Distribution Management, and the Canadian Association of Chain Drug Stores attended the meeting.
- The letter indicates a willingness to report to the Minister on the progress made by this group in the coming months.

Recommended Path Forward

Industry Analysis

- Objective: To further investigate the international models for notification, communication and management of drug shortages.
- Next Step: The Department will contact international partners in the US, Europe and Australia.
- Next Step: Pursue contract for further analysis of pharmaceutical supply chain

Industry Leadership

- Objective: Industry associations and CPhA partner to put in place a shortages communications tool
- Next Step: Commend CGPA for taking this leadership opportunity and monitor progress of the industry-led working group

Conclusion

- Based on our current understanding of drug shortages, the impact is felt more by the practitioner than the patient – it is an administrative challenge more than a direct health challenge.
- As such, Health Canada is supportive of a stakeholder-led, voluntary approach to communicating drug shortages; this is preferred to a regulatory action.

11-109054-225

Debrief and Follow-Up of Internal Meeting or Teleconference
with the Minister's Office

Discussion: Drug Shortages

Meeting/Teleconference Information	
Purpose of Meeting	**Date**
To provide MO with an update on where the department is at with respect to the drug shortages issues.	May 12 at 10:00
MO Staff in Attendance	**Portfolio Participants**
Leah Canning, Scott Tessier, Andrea Paine, Tim Vail, Carlo Oliviero, Erin McClelland, Jenny VanAlstyne, Clarke Olsen, Graham Howell	HPFB : Kendal Weber, Joanne Garrah SPB : Jean Pruneau, Hayden Lansdell PACCB: Charles Mojsej DMO: Christine Gillis, Martina Vorel
High level summary of discussion:	
HPFB and SPB provided an update on key activities since the MO's was last briefed on addressing the drug shortage, including the CADTH Environmental Scan, and discussed options for moving forward. Discussion also included trends in drug shortages as well as international comparisons.	

Follow-up			
Follow-up Item	**Lead**	**Status**	**Date submitted or Date due in MO**
Refresh messaging, i.e. media lines, correspondence responses, based on what we're doing and communicate constraints.	HPFB/SPB		
Brief Minister upon her return, or new Minister, as the case may be.	MO		TBD
Include drug shortages as an agenda item for the DM's meeting in June.	DMO		

Prepared by: Martina Vorel
Date Prepared: May 12, 2011

FOR INFORMATION

11-109537-698

BRIEFING NOTE TO THE MINISTER'S OFFICE

Drug Shortages

ISSUE:

The Minister's Office has requested a briefing note on the following:

1 - Article 81 of European Directive 2001/83 as well as the actions the UK took in 2005 to implement the directive;

2 - The applicability of the UK's recent publication of a best practices document to the Canadian regulatory system; and,

3 - A summary of the bill proposed in the US Senate this past February addressing drug shortages.

RESPONSE:

Questions 1 and 2:

Directives at the European level stipulate two major requirements for member states with respect to drug shortages:

- **Notification:** [Article 23a, Directive 2001/81] the holder of a market authorization must notify the regulator no less than two months before any temporary or permanent supply interruption, except in extraordinary circumstances; and,

- **Continuity of supply:** [Article 81, Directive 2001/83] the holder of a market authorization and distributors of a medicinal product ensure appropriate and continued supply to pharmacists and other authorized dispensers so that the needs of patients in the member state are covered.

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The UK implemented these requirements into domestic law through two instruments:

- Changes were made to the *Medicines (Marketing Authorisations Etc.) Amendment Regulations* by making it an **offence** not to meet the requirements set out in Articles 81 and 23a of the EU Directives. The penalty for offences is as follows: for summary conviction, a fine not exceeding 5000 pounds; or on indictment, a fine or imprisonment not exceeding 2 years, or both. These levels are statutory maximums set by the *European Communities Act* 1972 (ECA); and,

- Changes were also made to the *Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations* requiring wholesalers to **ensure appropriate and continued supply**. For contraventions under these Regulations, the penalty is as follows: 400 pounds; or on indictment, a fine or imprisonment not exceeding 2 years, or both. These levels were made jointly under the *Medicines Act* 1968 and the ECA.

It is noteworthy that the medicines legislation in the UK is currently being consolidated.

To implement these changes to the legal framework, the UK Department of Health (DH) engaged key representatives throughout the health system and drug supply chain to assist in the development of the following supporting guidances:

Best Practice for Ensuring the Efficient Supply and Distributrion of Medicines to Patients (February 2011) - This guidance outlines the key roles of manufacturers, wholesalers, pharmacies and prescribers in supply interruption situations. In addition, a link is provided to the Pharmaceutical Services Negotiating Committee (a non-government body that negotiates contracts for the provision of pharmacy services in the UK), who takes responsibility for maintaining a list of shortage medicines, as well as recommending contingency measures in disruption situations.
http://www.psnc.org.uk/pages/ncso_supply_issues.html

Trading Medicines for Human Use: Shortages and Supply Chain Obligations (December 2010) - This publication sets out the key legal and ethical obligations on manufacturers, wholesalers, pharmacies and others in relation to the supply and trading of medicines.

Notification and management of medicines shortages - Best Practices Guidelines (January 2007) - This is a voluntary best practices guidance, and includes recommended

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steps to take in a shortage situation, as well as providing a key point of contact at the DH and an electronic form to facilitate the communication of shortage information. The DH treats information about supply interruptions as confidential, and does not make this information publicly available. Communication regarding shortages is left in the hands of the companies.

Applicability to the Canadian Context

The UK guidance documents represent an extremely helpful example of a multi-sector, collaborative approach to set out best practices for those who supply, distribute, prescribe and dispense drugs so that patients are not jeopardized by shortages. The documenting of similar practices in a collaborative way in the Canadian context would be similarly beneficial, with participation and leadership by all key sectors.

One of the most appealing aspects of the UK approach that can be argued as highly suitable in Canada, is that the guidance documents are consistent and clear that it is really up to those who supply, distribute, prescribe and dispense drugs to ensure that an appropriate and continued supply reaches patients, and that shortages are managed with best practices in the interests of patients. (This stands in [redacted] contrast to the U.S., for example, where the regulator takes a more interventionist, hands on approach in governing notice and in mitigating supply issues.)

Question 3:

United States

The Drug Shortages Program in the U.S. was established to address potential or actual shortages of prescription, over-the-counter, or generic drugs that have a significant impact on public health. The program gets information about shortages from health care professionals, patients, professional organizations or manufacturers on a voluntary basis. The US FDA also maintains a webpage listing shortages of primarily medically necessary products and also includes an RSS feed on current supply interruptions; links to other helpful sites (e.g. the ASHP drug shortage listing and its guidelines); mechanisms to report shortages, as well as a guide for internal staff.
http://www.fda.gov/drugs/drugsafety/drugshortages/default.htm

Senate Bill 296, *To amend the Federal Food, Drug and Cosmetic Act to provide the Food and Drug Administration with improved capacity to prevent drug shortages*, was tabled on February 7, 2011.

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The proposed Bill includes the requirement to **notify the regulator six months prior** to a planned supply interruption or as soon as possible for an unplanned interruption.

Additionally, the regulator would develop criteria to identify drugs vulnerable to a supply shortage, collaborate with manufacturers of these drugs to address drug shortages, as well as communicate information on the actual shortage to the public. The proposed Bill was referred to the Committee on Health, Education, Labor and Pensions. There has been no publicized follow-up since February.

It may be worth noting that some collaborative developments on a more administrative level have been developing in the U.S other than formal legislation.

For example, the **American Society of Health-System Pharmacists (ASHP)** in the US has expanded on the type of shortage communication activities that are conducted by the PSNC in the UK. The ASHP works with partners to keep the public informed of the most current drug shortages by collecting and publishing shortage information by category: "Current", "Resolved" or "Drugs no longer available". Information communicated includes: Products Affected; Reason for the Shortage; Estimated Resupply Dates; Implications for Patient Care; Safety; Alternative Agents & Management; and References. Links are also provided to helpful publications to assist in managing supply interruptions.
http://www.ashp.org/menu/PracticePolicy/ResourceCenters/DrugShortages.aspx

Deputy Minister's Office

MECS# 11-109537-698

Branch Head: Paul Glover, ADM, Health Products and Food Branch
Telephone: 613-957-1804

FOR A MEETING

11-109221 - 348

BRIEFING NOTE

Meeting with Jeff Morrison, Director of Government Relations and Public Affairs of the Canadian Pharmacists Association (CPhA) at 2pm on Tuesday, June 14, 2011

ISSUE:

The CPhA requested this meeting to touch base and share information on a number of Health Canada-related issues and developments, including;

- Upcoming expiration of the Health Accord;
- Drug Shortages;
- Progressive Licensing;
- Impact of the Federal election; and
- Upcoming international meeting of senior health officials organized by the International Pharmaceutical Federation

BACKGROUND:

Organization

CPhA is the national organization for pharmacists, advocating and supporting its members to advance the profession and enhance patient outcomes.

Jeff Morrison is the Director of Government Relations and Public Affairs.

CPhA has, over the last year, expressed an interest in discussing a number of issues with the department, including: drug shortages, pharmaceutical policy, expiration of the 2004 health accord, regulatory modernization, and lessons learned from the H1N1 pandemic planning.

In 2009, Health Canada provided $300,000 to CPhA to create a new national website as part of their Blueprint for Pharmacy.

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Previous Meetings on relevant topics

February 16, 2011 - Parliamentary Secretary to the Minister of Health Dr. Colin Carrie met with the CPhA to discuss recent international developments that affect the pharmacy industry.

January 27, 2011 - The Minister of Health met with Jeff Poston, Executive Director of CPhA Regarding Drug Shortages; the Expiry of the 10 Year Health Accord; and Role of the Pharmacist in the Ministerial Boardroom.

October 27-28, 2010 / November 30-December 1, 2010 / January 19-21, 2011 - Technical Discussions on Regulatory Modernization for Therapeutic Products - representatives from the CPhA participated in these technical discussions. The sessions covered a broad range of topics, including pre-market submission requirements, transparency and information sharing, and post-market authorities;

November 24, 2010 - Dr. Colin Carrie met with CPhA to discuss the evaluation of the 2004 Health Accord, federal health transfers post-2014, drug shortages, and options to further utilize pharmacists in pandemics. On September 22, 2010, Dr. Carrie delivered a speech at a CPhA addressing drug safety and effectiveness, adverse drug reaction reporting, Canada Health Infoway, and federal health transfers.

November 19, 2010 - Meena Ballantyne met with Jeff Poston to discuss drugs shortages; the regulatory modernization exercises (Technical Discussions on Regulatory Modernization); evidence based drug information and electronic decision supports.

October 6, 2010 - representatives from the CPhA met with representatives from the Health Products and Food Branch (HPFB) as part of the Bilateral Meeting Program. The agenda included a discussion of drug shortages and their impact on patient care.

Recent Correspondence

March 11, 2011 - The Minister of Health wrote a letter to the Canadian Generic Pharmaceutical Association (CGPA), Canada's Research-Based Pharmaceutical Companies (Rx&D), and BIOTECanada requesting that members "voluntarily provide information on drug shortages". Stakeholders have responded with interest in discussing this issue further with Health Canada. CGPA also informed of a recent (April 18, 2011) multi-stakeholder working group meeting they hosted to discuss the issue of drug shortages with representatives from CGPA, Rx&D, BIOTECanada, CPhA, Canadian Society of Hospital Pharmacists, Canadian Medical Association, Canadian Association of Pharmacy Distribution Management, and the Canadian Association of Chain Drug Stores.

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To be sent shortly - The Minister of Health will be sending a second letter to these stakeholders with the following key messages:

- Encouraging their continued collaborative efforts
- Asking that they involve officials from Health Canada in discussions moving forward
- Noting that an effective reporting mechanism should be compulsory, timely, and comprehensive; otherwise, a regulatory requirement for the disclosure of shortage information may be necessary

Consultation

The CPhA attended the Technical Discussion Sessions on Regulatory Modernization that were hosted by OLRM between October 2010 and January 2011. At the October session, one topic was devoted to access issues, generally including:

- **Drug shortages** - in cases where there is only one manufacturer and the drug is used to treat a serious or life-threatening condition, the market authorization holder would be required to notify the regulator of anticipated or occurring shortages.
- **Drug discontinuances** - in cases where there is only one manufacturer and the drug is used to treat a serious or life-threatening condition, the market authorization holder would be required to notify the regulator 6 months in advance of discontinuing manufacturing of a drug.
- **Disclosure of this information** - it was proposed for discussion that the regulator make information about shortages and discontinuances available through the proposed "Product Register" (online database system containing all information about a therapeutic product in one location).

Mr. Poston spoke to the impact of drug shortages on the practice of pharmacy, and ultimately patient care. He also identified the absence or delay in communication of information on drug shortages from manufacturers as being a significant factor affecting the management of drug shortages.

Other industry stakeholders were not in full agreement with the proposal to require a notification of drug shortages, noting that such a regulation would not be flexible enough to accommodate such a complex situation.

CONSIDERATIONS:

Speech from the Throne - the June 3rd speech did not explicitly commit to modernizing the legislation or regulation of health products and food; however, there was an indirect reference to supporting the "efforts of the Public Service to modernize the way it works

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so that it can continue to provide the highest standard of service to Canadians", as well as, "maintaining the healthiest standards to protect our environment and the health and safety of Canadians" through initiatives like cutting red tape for small businesses.

HPFB Regulatory Roadmap - HPFB is currently developing a Regulatory Roadmap to help guide the transformation of the regulatory frameworks for all health products and food, and help explain our vision and plan to stakeholders, Canadians, and our international counterparts. As an example, we aim to expand the lifecycle model (introduced through the Progressive Licensing Project) for drugs to all products we regulate. Other initiatives such as Red Tape Reduction and the Regulatory Cooperation Council will also play into the context of this work.

Meeting Strategy:

General

- You may wish to request an update on the CPhA's recent initiatives related to drug shortages including their April meeting with generic and brand name drug manufacturers and distributors, and the member poll from last fall on the impact of drug shortages.

- The CPhA may request an update on the Department's efforts to advance legislative proposals for food and drugs. They may also be interested to know how the recent Technical Discussions on Regulatory Modernization impact on or are related to these efforts. You may wish to raise the current work underway to develop HPFB's Regulatory Roadmap.

- You may wish to highlight that the proposals presented at the Technical Discussions on Regulatory Modernization (and the related stakeholder feedback) will be used to support our continuing efforts to advance regulatory proposals for food and drugs.

Issue-specific

Impact of the Federal election

- We are pleased to continue working with Minister Aglukkaq on health issues that are important to Canadians.
- The Speech from the Throne re-iterated the government's commitment to maintain the direction established in previous minority governments.

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Upcoming international meeting of senior health officials organized by the International Pharmaceutical Federation (FIP)

- On October 3, 2012, FIP will be hosting a Ministerial Summit on pharmaceutical policy and Meena Ballantyne was invited to attend.
- All responses from HPFB have re-directed the invitations to Canada's Geneva-based Health representative, Ms. Joanne Hamilton, as well as the Strategic Policy Branch's Director General of the International Affairs Directorate, Ms. Bersabel Ephrem.

NEXT STEPS:

HPFB will continue to consult with CPhA on any draft regulatory proposals, and looks forward to their participation in the development and implementation of the Regulatory Roadmap for health products and food.

Director General: Kendal Weber
Telephone: 952-8149

Contact: David K Lee
Telephone: 946-6586

Attachments: (3)
Appendix A - Expiry of the 2004 Health Accord
Appendix B - Drug Shortages
Appendix C - Progressive Licensing

Appendix A

EXPIRY OF 2004 HEALTH ACCORD

Issue:

The CPhA would like to hear the process for renewing the 2004 Health Accord, and what might be contained in such an Accord.

Organization's position:

The CPhA is advocating for a formal new Accord consultation process similar to federal budget consultations.

Health Canada's position:

The CPhA will have the opportunity to appear before the 2011 mandated Parliamentary Review of the 2004 Accord, and regularly engage Health Canada's senior management.

Key Messages:

- The Speech from the Throne announced a commitment to "working with the provinces and territories to ensure that the health care system is sustainable and that there is accountability for results... while working collaboratively with provincial partners to renew the Health Accord...".

- As part of the Federal Government's responsibility towards the health and safety of Canadians, HPFB's Regulatory Roadmap will lead the way to a sustainable and effective regulatory system for health products and food.

Appendix B

DRUG SHORTAGES

Issue:
In September 2010, the CPhA initiated an online survey of its membership on drug shortages in Canada. The report, released on December 15, 2010, highlighted the impact of drug shortages on patients and health professionals. It recommended more timely and accessible notification of drug shortages.

Organization's position:
The CPhA has identified the absence or delay in communication of information on drug shortages from manufacturers as being a significant factor in drug shortages. In the face of shortages, the CPhA requested an expanded scope for pharmacists to provide different treatment plans.

Health Canada's position:
Drug supply problems are not uncommon. They may be caused by disruptions in the supply chain, shortages of raw materials, delays due to regulatory requirements, or business decisions by drug companies.

Supply interruptions are generally dealt with by industry and health professionals. A limited number of these will result in shortages that lead to treatment interruptions.

Health Canada has undertaken work in recent months to better understand its role in responding to drug shortages and to identify potential opportunities to improve communication and management of drug shortages. This work will continue.

Key Messages:
- If Health Canada becomes aware of a critical shortage on an important drug, the Department works with manufacturers and the medical community to minimise the impact of the shortage and facilitate access to alternatives.

- As you are aware, Minister Aglukkaq has written to industry to ensure a collaborative approach on this important issue.

- Health Canada will continue to work with industry, provinces and territories, and the medical community, and act within its power as the drug regulator to reduce the impacts of shortages to the extent possible.

Appendix C

PROGRESSIVE LICENSING (PL)

Issue:
The CPhA would like to know about the status of the PL initiative and any work to modernize the regulatory system.

Organization's position:
CPhA has supported the process of regulatory modernization by being engaged in both the Progressive Licensing consultations and Technical Discussion Sessions. They are generally supportive of the lifecycle model.

Health Canada's position:
We aim to expand the lifecycle model for drugs to all products we regulate, and continue the work to develop a sustainable and effective regulatory system.

Key Messages:

1. HPFB initiated the Progressive Licensing Project to assess areas for improvement and consult with relevant stakeholders including industry, ends users and the public.

2. Building on the work and consultations accomplished through the Progressive Licensing Project and the Technical Discussions, HPFB is now in a position to proceed with its Regulatory Roadmap.

3. HPFB is appreciative of the valuable input and feedback of CPhA on these initiatives, and looks forward to engaging further as we develop the Regulatory Roadmap.

4. Other initiatives such as Red Tape Reduction and the Regulatory Cooperation Council will also play into the context of this work.

11-111180-121

Debrief and Follow-Up of Internal Meeting or Teleconference
with the Minister's Office

VB: Discussion on Drug Shortages

Meeting/Teleconference Information	
Purpose of Meeting	**Date**
To obtain updates on drug shortages from the DMs discussion on the subject at a recent FPT meeting.	June 16, 2011
MO Staff in Attendance	**Portfolio Participants**
Graham Howell **Carlo Oliviero**	**SPB : Barbara Moran** **HPFB : Etienne Ouimette** **DMO : Christine Gillis**
High level summary of discussion:	
HFPB/SPB provided a quick overview of discussions from the last FPT meeting where Drug Shortages was discussed. They advised that the key message from HC at that meeting we "HC will continue to gather info on drug shortages and share info with provinces and territories."	

Follow-up			
Follow-up Item	**Lead**	**Status**	**Date submitted or Date due in MO**
Provide MO with next steps/upcoming items on this issue	HPFB		June 21, 2011

FOR A MEETING

11-111374-25

BRIEFING NOTE

Meeting with the Canadian Generic Pharmaceutical Association
at 1:30 p.m. - 3:00 p.m. on Tuesday, June 21, 2011

ISSUE:

The Canadian Generic Pharmaceutical Association (CGPA) has requested a meeting with the Health Products and Food Branch's (HPFB) Assistant Deputy Minister (ADM) to discuss four topics: a joint collaborative initiative, the proposal to eliminate the Notifiable Change (NC) category, performance for the review of Abbreviated New Drug Submissions (ANDS) and Drug Shortages.

BACKGROUND:

Organization:

CGPA represents manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry.

Previous meetings:

The CGPA met with the Deputy Minister's Office on March 23, 2011. CGPA also routinely participates in bilateral discussions with several HPFB directorates, including the Therapeutic Products Directorate (TPD) and on a more technical level with the Bureau of Pharmaceutical Sciences (BPS). Meetings are often at the transactional level and concern issues of mutual interest around the regulatory process, but also touch on the Branch's strategic directions. The Bureau of Pharmaceutical Sciences met with the CGPA on April 27, 2011. At this meeting, the BPS provided an update on review status, as well as other operational issues, as specifically described below. The next TPD - CGPA meeting will be on June 27, 2011.

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Recent Correspondence:

On April 4, 2011, the CGPA sent a letter to follow up on the meeting with the Deputy Minister. In this letter, the CGPA refers to Health Canada's agreement to work collaboratively with the CGPA on process improvement to ensure the reduction of review backlogs. There has been no indication within the department that this agreement took place. When CGPA suggested a collaborative process to the Deputy, her response was that rather than start what could be a long process, if CGPA had suggestions as to how review performance could be improved they should provide these to Mr. Paul Glover ADM - HPFB. The CGPA has also proposed new timelines for the review of specific categories of submission, and hopes to be involved in any process improvement effort that the Therapeutic Products Directorate undertakes.

Consultations:

The HPFB meets regularly with industry associations to discuss issues and topics of mutual interest. The TPD meets not only with the CGPA, but also Rx&D, who represent innovator companies, and other smaller associations.

CONSIDERATIONS:

1. Joint Collaborative Initiative and ANDS Performance (and Supplemental Abbreviated New Drug Submission (S/ANDS) Performance)

In April 2011, the CGPA submitted to Health Canada, a document entitled: "Drug Review Times: Developing a Sustainable Solution" (Appendix A). In this document, the CGPA proposes a collaborative approach to resolving the long standing backlog issues, and includes strategic objectives and seven recommendations with timelines designed to help the Therapeutic Products Directorate reduce the backlog. CGPA have noted concerns on how the backlog impacts patient access to new generics and the cost to the overall healthcare system.

Health Canada has been experiencing a significant increase in volume of generic pharmaceutical submissions (i.e. ANDS) and with the number of drugs coming off patent, this trend is expected to continue for the next few years. It is estimated that for each new drug coming off patent, eight generic submissions are received. A relatively stable level of resources has allowed for a stable number of review decisions but is insufficient to address the increasing volumes. Currently, approximately 55% of the generic drug workload is in backlog. Cost recovery revenues are expected to address the inadequate resourcing at the Therapeutic Products Directorate for ANDS.

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During the April 27, 2011 bilateral meeting between BPS and the CGPA, BPS identified ways generic companies can help improve review times. These included using the Canadian Quality Overall Summary - Chemical Entities (QOS-CE) more effectively to improve efficiency of the review process. Also, and from an administrative perspective, using the QOS-CE summaries and providing well formatted eCTDs (electronic Common Technical Documents) will allow for easier review navigation.

The CGPA has also raised concerns about "unique Canadian requirements" in the past. The BPS re-iterated its request for information on these requirements.

2. Proposal to Eliminate the Notifiable Change Category of Submissions

The program has struggled with the volume of pharmaceutical Notifiable Changes (NCs) specifically. Only 10-25% of submissions were reviewed on time over the last six quarters and the backlog is approximately 47% of total NC workload. NCs are not a category of submission in the regulations; thus, there is no mechanism to correct negative compliance.

A proposal to eliminate the NC category has been published on Health Canada's Web site. Of the approximately 800 comments received, approximately 25% have been reviewed and draft revisions made to the proposal as necessary. We estimate the review will be complete by the end of July 2011.

The CGPA is not in support of the proposal to eliminate Notifiable Changes. The concern of the CGPA is centered around two issues:

- The CGPA estimates that approximately 50% of submissions that will be re-categorized from NCs to S/ANDS will trigger the Patented Medicines (PM)(NOC) Regulations, consequently increasing costs for generic manufacturers.

- Health Canada risks making the backlog situation worse by moving submissions from the NC category to the S/ANDS category.

While the TPD agrees that the PM(NOC) Regulations will be triggered more regularly by the removal of the NC category, this is seen as closing a loophole previously created by the NC category, which does not trigger the PM(NOC) Regulations.

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With respect to the concern of the CGPA that the elimination of the NC category will increase workload without the addition of resources, we confirm that resources currently assigned to the review of NC submissions will be re-assigned to the review of S/ANDS.

It is also worth noting that fees for NCs were not part of the Cost Recovery Proposal. Elimination of the category will mean that the submissions will be reviewed as S/ANDS with a performance target of 180 days and will be cost-recovered.

3. Reports of Shortages of Some Drug Products

The Department has received several reports and considerable correspondence on the issue of drug shortages. The reports suggest drug shortages are more common in generic products. This meeting provides an opportunity to seek the Association's input on the potential causes of drug shortages, and to identify opportunities to improve the management of drug shortages; for example, through the development of industry best practices for preventing, managing and communicating information on drug shortages. Communication of potential shortages to associations such as the Canadian Pharmacists Association (CPhA) and National Association of Pharmacy Regulatory Authorities (NAPRA) would also be helpful.

Health Canada has undertaken work in recent months to better understand its role in responding to drug shortages and to identify potential opportunities to improve communication and management of drug shortages. This work will continue.

Meeting Strategy:

The CGPA may be coming to this meeting to strongly advocate for an initiative in which they have more direct input into how Health Canada reviews generic drug submissions. Based on the letter of April 4, 2011, the CGPA interpreted the Deputy Minister's comments in the March 23, 2011, meeting as support for such a collaborative initiative, although this interpretation does not agree with TPD's record of the meeting. It will be important to demonstrate to the CGPA that we are taking the backlog issue seriously and are developing concrete, measurable plans to address the issues. Without making a commitment to embark on a collaborative initiative, CGPA could be invited to submit concrete proposals as to how to improve review performance. It is possible that the CGPA will again contact the DM should they feel that inadequate action has been taken by the TPD.

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This meeting is an opportunity to highlight some of the measures currently being undertaken by BPS to increase the workforce to deal with the increasing number of submissions including:

- the addition of 10 new chemist positions to increase review capacity in chemistry and manufacturing;
- the investigation of options for a satellite office to attract high quality reviewers with significant manufacturing experience;
- the investigation of process improvement options to streamline submission review with a focus on key areas of concern.

NEXT STEPS:

HPFB will continue to consult with CGPA, and looks forward to their positive participation and contributions.

Director General: Supriya Sharma
Telephone: 613-957-6466

Contact: Katie Greenwood
Telephone: 613-946-6829

Originator: Katie Greenwood/Andrew Adams
Telephone: 613-946-6829/613-948-4273

Attachments:

Appendix A - Drug Review Times: Developing a Sustainable Solution Submission
Appendix B - Key Messages

Canadian Generic Pharmaceutical Association

CGPA GENERIC DRUGS SAME QUALITY BETTER PRICE

Drug Review Times
Developing a Sustainable Solution

A Submission to Health Canada

April 2011

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Introduction

Canada's federal generic drug review system is not providing timely drug reviews. In fact, Health Canada is not meeting its own performance targets. This situation is long standing and the consequent impacts are both significant and wide ranging. They include:

- Increased drug costs;
- Reduced availability and a lack of continuity of drugs in the health-care system; and
- Increased business uncertainty, with a consequent dampening of investment in plant, machinery and people.

The Canadian generic pharmaceutical industry believes that the federal standards that have been established to ensure the safety, efficacy and quality of Canadian generic drugs are world class. Unfortunately, the regulatory system is failing to achieve these standards within reasonable timeframes.

A review of the history of dealing with this issue during the past two decades demonstrates that:

- The situation has been well documented;
- Observers on both sides are in agreement about the fact that there is a performance shortfall;
- Most of the proposed changes have been tactical in nature rather than strategic and long lasting; and
- Implementation efforts of agreed changes have often stalled.

The challenge of timely drug reviews has received the attention of many studies including those emanating from Directorates within Health Canada, its Science Advisory Board, and the Auditor General of Canada. More studies are not the solution. Nor are piecemeal changes that have the effect of fixing one problem and opening up another.

The Canadian Generic Pharmaceutical Association (CGPA) believes that it is timely to approach the issue of drug review delays in a more fundamental manner. We believe that what is required is a collaborative approach that, while identifying meaningful interim solutions to the most pressing issues affecting the system, such as the back log in Notifiable Changes, is directed at a major process improvement initiative of the drug review system.

We believe that this Industry – Federal Government Initiative should be designed to achieve agreed long-term objectives. We put forward as a set of strategic objectives the following:

By December 2013, we will strengthen the capacity of the drug review system to meet the quality, efficacy and safety requirements of the regulatory process, within the following timeframes:

- *Abbreviated New Drug Submissions (ANDS)..... Review completed in 225 days.*
- *Supplemental Abbreviated New Drug Submissions (SANDS).. Review completed in 225 days.*
- *Notifiable Changes (NC)..... Review completed in 90 days.*

We are proposing an initiative that will provide many benefits. It will deliver solutions to the problem cited above and as well create an environment that Health Canada employees can be proud to work in. In addition, the process improvement approach will foster improved industry-government synergies. Finally, it will create a system that will be respected internationally for its operational effectiveness as well as its high review standards.

We, therefore, recommend the following:

1. The CGPA will collaborate with Health Canada to achieve the strategic objectives noted above;
2. To undertake an end-to-end process improvement initiative;
3. Taking into account the expected increase in resources from updated cost recovery measures;
4. The initiative would identify process weaknesses and process opportunities including supporting tools (guides) for industry and staff etc;
5. With a goal of identifying and implementing meaningful interim measures to address critical issues including the backlog in Notifiable Changes by September 2011;
6. And of completing the full process design and implementation actions by September 2012; and
7. The realization of improved performance targets by December 2013.

This document acknowledges the range of technical issues that have been reviewed and discussed during the past 10 years.

Finally, the document provides an overview of the recommended actions for a major process improvement initiative.

A Brief History and Current Situation

Generic Drugs

Canada's federal generic drug review system has been chronically under-resourced for years leading to delays in the review of generic drugs and creating a backlog of generic drug submissions.

These delays and the lack of predictability in the review process create an environment of uncertainty for drug companies as they strive to create production and marketing plans that will introduce lower-priced generic products to Canadian consumers and the health-care system.

An effective and efficient drug review process would improve the availability of lower priced generic products to consumers and the health-care system, alleviate pressure on Health Canada staff, and provide generic drug companies with a predictable and stable business environment.

Health Canada is Unable to Meet Its Own Performance Targets....

Health Canada is currently unable to meet its own targets for reviewing generic drug submissions. In 2009 the generic drug industry filed 179 submissions for new generic drugs (Abbreviated New Drug Submissions). Less than half – 45% – of these were reviewed by Health Canada within its 225 day performance target. This, notwithstanding the fact that generic drug companies paid over $8 million in user fees; contributing half the costs of the generic drug review process. By 2010, fewer than one in five generic drug submissions were reviewed within 225 days and almost half of all generic drug submissions were in backlog.

Drug Review Times
Developing a Sustainable Solution

Percentage of Drug Reviews that Met Health Canada Performance Targets[1]

	2005	2006	2007	2008	2009	Q1 2010	Q2 2010	Q3 2010
Brands – New Drug Submissions (NDS)	62%	84%	92%	88%	71%	64%	72%	84%
Generics – Abbreviated New Drug Submissions (ANDS)	64%	90%	92%	90%	45%	33%	23%	19%

The generic drug review process is both unnecessarily long and unpredictable. While Health Canada's target for generic drug reviews is 225 days, in 2009 reviews ranged from 210 days to over 3 years.

Percentage of Drug Reviews in Backlog[2]

	2005	2006	2007	2008	2009	Q1 2010	Q2 2010	Q3 2010
Brands – New Drug Submissions (NDS)	4%	0%	0%	12%	8%	8%	10 %	16%
Generic – Abbreviated New Drug Submissions (ANDS)	0%	3%	6%	5%	35%	43%	46%	48%

[1] Therapeutic Products Directorate. Drug Submission Performance Annual Report January – December 2009 and Drug Submission Quarterly Report July – September 2010.
[2] Therapeutic Products Directorate. Drug Submission Performance Annual Report January – December 2009 and Drug Submission Quarterly Report July – September 2010.

Health Canada Lacks the Resources To Do Its Work ....

The number of generic drug submissions reviewed by Health Canada has increased by 31% in the last five years and by 200% in the last decade but resources have not kept pace. Today, Health Canada has just 73% of the funding required to conduct its drug review activities.[3]

In its recent review of user fees for human drugs and medical devices, Health Canada determined that user fees for generic drugs have, in large measure, reflected 50% of the costs associated with generic drug review activities. Notwithstanding that, total user fees account for just 27% of the total cost of drug submission evaluations – well short of the government's 50% target for cost recovery.[4] A short-fall in funding for brand name drug reviews has diverted resources away from other activities, including the review of generic drug submissions, and contributed to delays and backlogs across the entire drug review system.

The Problem is Long-Standing.....

Lack of timely drug reviews has been a recurring problem for Health Canada over the past two decades.

In 1987 the Stein Committee concluded the most pressing problem associated with drug submission reviews was the review backlog and that a special task force should be appointed to address the problem.[5]

In his 1992 report *Working in Partnerships...Drug review for the future*, Denis Gagnon found that 48% of the Bureau for Human Prescription Drugs workload was in backlog[6] and that the backlog of generic drug submissions had been increasing steadily.[7]

[3] Cost-Benefit Analysis: Proposed Fees in Respect of Human Drugs and Medical Devices Regulations. Health Canada. October 2010. Executive Summary.
[4] Cost-Benefit Analysis: Proposed Fees in Respect of Human Drugs and Medical Devices Regulations. Health Canada. October 2010. Executive Summary.
[5] Working in Partnerships...Drug review for the future. Review of the Canadian Drug Approval System. July 1992. Page 69.
[6] Working in Partnerships...Drug review for the future. Review of the Canadian Drug Approval System. July 1992. Page 69.
[7] Working in Partnerships...Drug review for the future. Review of the Canadian Drug Approval System. July 1992. Page 92.

In its 2000 report, the Committee on the Drug Review Process of the Science Advisory Board to Health Canada again found that drug review times were too long and that the process needed improvements to its "timeliness, efficiency, and effectiveness".[8] The Committee found that there were insufficient human and financial resources allocated to the drug review process[9] and recommended that Health Canada move to a 50:50 ratio of cost recovery fees and appropriations for drug reviews, as was the original intent of cost recovery.[10]

In 2006, the Auditor General of Canada's review of the Drug Product Program concluded that Health Canada could not demonstrate that it had adequate financial resources for its drug products program and that core funding for that program had decreased 32% over three years.[11]

The lack of adequate funding for drug reviews has crippled the review process and hindered the ability of drug companies to effectively plan for the release of new drugs.

...and the problem will only get worse

The generic drug industry expects the number of generic drug submissions to continue to grow.

Drug Submissions by Year[12]

	2005	2006	2007	2008	2009	2010 Q1-3
Brand Drugs	51	53	51	53	64	35
Generic Drugs	137	124	142	161	179	135

[8] 2000 Report of the Committee on the Drug Review Process of the Science Advisory Board to Health Canada. Page 6.
[9] 2000 Report of the Committee on the Drug Review Process of the Science Advisory Board to Health Canada. Page 13.
[10] 2000 Report of the Committee on the Drug Review Process of the Science Advisory Board to Health Canada. Page 12.
[11] November 2006 Report of the Auditor General of Canada to the House of Commons. Chapter 8 Allocating Funds to Regulatory Programs -- Health Canada. Page 10
[12] Therapeutic Products Directorate. Drug Submission Performance Annual Report January – December 2009 and Drug Submission Quarterly Report July – September 2010.

The generic industry is competitive and the rate of new companies entering the market and of products developed is high. Proposals to Health Canada for generic drug submissions consistently outnumber brand products three to one. As well, the number of generic medicines being developed is expected to increase over the next few years due to patent expirations on a number of brand drugs and the resolution of legal claims under the Patented Medicines (Notice of Compliance) Regulations. The introduction of private label drugs will also increase the number of generic applications received by Health Canada and place even more pressure on a system that is already overwhelmed.

Post-Notice Of Compliance Changes: Supplementary New Drug Submissions (SANDS) and Notifiable Changes

As with new generic drug submissions, Health Canada is not meeting its own performance targets for post-market changes to approved drugs.

It is not uncommon for drugs to undergo changes to dosage, specifications, packaging, manufacturing, etc., after they have been approved for release into the market. The more serious of these changes must be approved by Health Canada before they can be implemented. Failure to approve post-market changes in a timely manner constrains companies' production and business decisions and can lead to shortages of drug products.

In a global manufacturing environment, changes to manufacturing locations, processes, or suppliers are often made with short lead-times. A responsive regulatory review and approval process helps to ensure a stable and predictable supply of drugs to Canadian consumers and the health-care system.

The Review Process for Drug Changes is Under Pressure...

Health Canada has adopted a risk-based, tiered structure for introducing changes to drugs that have already been approved and are on the market. Proposed drug changes are grouped into four categories based on their potential impact on safety and efficacy.

Level 1	Level 2	Level 3	Level 4
Supplementary Abbreviated New Drug Submissions (SANDS)	Notifiable Changes (NC)	Annual Notifications	Record of Changes
Substantial potential to impact the safety or effectiveness of the drug.	Moderate potential to impact the safety or effectiveness of the drug.	Minimal potential to impact the safety or effectiveness of the drug.	Not expected to impact the safety or effectiveness of the drug.
Cannot be implemented until Health Canada issues Notice of Compliance	Cannot be implement until Health Canada issues No Objection Letter	May be implemented without prior review by Health Canada but Health Canada must be notified.	Company must retain information as part of its own internal records.

Level 1 Supplemental Abbreviated New Drug Submissions (SANDS) and Level 2 Notifiable Changes (NC) cannot be implemented without Health Canada approval and must undergo rigorous reviews by Health Canada staff. The numbers of Level 1 (SANDS) and Level 2 (NC) changes have been increasing almost steadily since 2005 and continue to grow. Since 2005 the number of Level 1 Supplemental Abbreviated New Drug Submissions changes has increased four-fold from 7 to 32 submissions. Level 2 – Notifiable Changes (used by both generic and patent drug manufacturers) have increased by almost 25% to over 1,000 submissions a year.

Number of Submissions to Health Canada, by Year[13]

	2005	2006	2007	2008	2009	% Change
SNDS (Brand Drugs)	133	189	150	153	131	-1.5%
SANDS (Generic Drugs)	7	26	12	19	32	457.1%

	2005	2006	2007	2008	2009	% Change
NC – Chemistry &Manufacturing	547	659	546	510	597	9.1%
NC – Label & Product Monograph	322	368	378	486	469	45.7%
NC – Safety & Efficacy	0	0	0	0	7	
Total NC's	869	1027	924	996	1073	23.5%

In the last two years, Health Canada has been unable to meet its own performance targets for reviewing changes to drugs that are already on the market.

In 2009 just 68% of all Level 1 – Supplemental Abbreviated New Drug Submissions filed by generic drug companies were reviewed within Health Canada's performance target of 225 days. By 2010, performance had deteriorated significantly and only 13% of submissions were reviewed in the time provided with almost half in backlog.

The record is dismal for Level 2 – Notifiable Changes. In 2010 only 73% of Notifiable Changes – Label & Product Monograph and only 10% of the generally more complex Notifiable Changes -Chemistry and Manufacturing were reviewed within Health Canada's 90 day target. Health Canada does not produce statistics on the length of the delay in reviewing Notifiable Changes but industry estimates that reviews commonly take between eight and nine months and, in some cases, over a year. It is clear that the system for reviewing Notifiable Changes has failed.

[13] Therapeutic Products Directorate, Drug Submission Performance Annual Report January – December 2009 and Drug Submission Quarterly Report July – September 2010.

Percentage of Drug Reviews that Meet Health Canada Performance Targets[14]

	2005	2006	2007	2008	2009	Q1 2010	Q2 2010	Q3 2010
Supplemental Drug Submissions								
Supplemental New Drug Submission (Patent Drugs)	73%	92%	97%	92%	88%	78%	75%	77%
Supplemental Abbreviated New Drug Submissions (Generic Drugs)	57%	92%	95%	92%	68%	0%	74%	13%
Notifiable Changes	2005	2006	2007	2008	2009	Q1 2010	Q2 2010	Q3 2010
Chemistry & Manufacturing	66%	33%	6%	17%	6%	12%	22%	10%
Label & Product Monograph	35%	75%	67%	66%	61%	59%	58%	73%

The Volume of Post-Market Changes will Continue to Grow ....

The backlog of Level 1 and Level 2 changes will worsen with shifts in industry structure and growing pressure to reduce drug costs.

The generic drug system is under intense pressure in most markets, including Canada, to reduce its costs. The trend in all Canadian provinces is to lower prices. For example, in 2006 the government of Ontario reduced the amount it will pay for generic drugs to 50% of the brand drug price. This was reduced to 25% in 2010. Quebec reduced the price it will pay to 25% starting in October 2010 and BC is expected to reduce their ceiling price to 35% by July 2011. Other provinces such as Nova Scotia and Saskatchewan will announce their new pricing policies in the next few months.

[14] Cost-Benefit Analysis: Proposed Fees in Respect of Human Drugs and Medical Devices Regulations. October 2010. Page 5.

Increased globalization, supply chain fragmentation, and the drive to find lower costs suppliers, will lead to changes in manufacturing processes and ingredient sourcing. This will drive the number of changes to drug products already in the market and shorten the lead time for production changes. To continue meeting the demand for generic drugs, industry must be increasingly flexible and adaptable. An effective and timely regulatory system is required to respond to these new realities.

Delays Have Been Made Worse By One-off Changes ...

The drug review system is highly complex. A piecemeal approach to procedures and criteria will only shift problems from one drug review area to another and exacerbate the delay and backlog in federal drug reviews.

The drug industry saw this when, in 2009, Health Canada implemented changes to its review process for Level 2 Notifiable Changes. Prior to September 2009, drug companies were able to implement Level II drug changes after 90 days of filing a submission with Health Canada as long as Health Canada had not identified an objection. Notifiable Change reviews were processed in a manner that best balanced the department's work load and industry was not impacted by delays in the review process. Starting in September 2009 companies are now required to wait for Health Canada approval before a Notifiable Change can be implemented. However, no new resources were assigned to address this new workload and, as a result performance across all drug product reviews has suffered. Of note, no generic Notifiable Changes have been rejected since the policy change was implemented.

Delays in the review of generic drug submissions (Abbreviated New Drug Submission) is also adding to the number of Notifiable Changes. The Canadian Generic Pharmaceutical Association estimates that 20% of Notifiable Changes relate to new generic drug submissions that are backlogged in the review process. Given the extended time most drug reviews take, it is inevitable that companies will be faced with manufacturing, supplier, or other changes before a drug is even approved for market. Without a mechanism to introduce essential updates during the drawn out drug review process, companies are forced to file Notifiable Changes almost immediately upon approval of their generic drug application.

The Recent Proposal to Eliminate Notifiable Changes will likely make matters worse ...

On March 21, 2011 Health Canada released a proposal to amend the current process that drug companies follow in seeking approval of Level II Chemistry or Manufacturing Notifiable Changes. This proposal would eliminate Level II Chemistry or Manufacturing Notifiable Changes and re-categorize these as either Level I Supplemental Abbreviated New Drug Submissions (SANDS) or Level III Annual Notifications.

The generic drug industry appreciates that Health Canada recognizes the backlog of Notifiable Changes as a critical issue. However, the drug review system is a complex and interconnected set of processes. Dealing with one segment of the system in isolation runs the risk of triggering issues or exacerbating problems in other areas.

The generic drug industry is reviewing Health Canada's proposal and will provide a formal written response. However, after a preliminary review, we raise the following significant cautions:

- Health Canada advises that the proposal will shift 40% of all Chemical and Manufacturing Notifiable Changes (brand and generic) into the Level I SNDS (brand) or Level I SANDS (generic) categories. This would more than double the number of SNDS and SANDS submissions Health Canada received in 2009 from 163 to 402 files. In 2009 Health Canada approved only 64% of all SNDS and SANDS submissions within their performance targets. The record was similar to Q3 2010. It is unrealistic to think that doubling the volume of submissions – even with additional resources – will not exacerbate this problem.
- The proposal selectively disadvantages generic drug companies. Health Canada estimates that the proposal will shift a greater proportion (58%) of Notifiable Changes filed by generic drug companies into the Level I SANDS category. Last year, Health Canada approved only 13% of SANDS's within their performance target. Health Canada's drug review performance history demonstrates that the department has effectively placed a priority on brand drug submissions at the expense of generic drug submissions. If this practice continues, the Notifiable Changes proposal is likely to create even greater problems for generic drug companies.

- The proposal will trigger additional litigation as brand companies are expected to challenge the new SANDS's under the Patent Medicines (Notice of Compliance) Regulations. Health Canada's new policy will inadvertently create a competitive advantage for brand drug companies, significantly increasing costs to generic drug companies. The additional litigation will unnecessarily introduce a high degree of unpredictability in the review process and will thereby disrupt the supply of generic drugs, fuelling concerns over drug availability.
- The proposal could result in $5.8 million in additional administration and legal costs to the generic drug industry, which expects it will be required to file Notices of Allegation for an estimated half of the new (re-categorized Notifiable Changes) SANDS's.

The backlog of Notifiable Changes is a critical problem that must be addressed through a collaborative discussion and as part of a broader initiative to improve the processes and manage the resources assigned to the drug review system. The most recent proposal from Health Canada to eliminate Notifiable Changes runs the risk of creating further costs and challenges without alleviating significant pressure on the review system.

The generic industry is eager to develop a collaborative solution to the back log of Notifiable Changes and to work together with Health Canada to resolve this issue on a priority basis.

Building a Sustainable Solution

It is the strongly held view of the Canadian Generic Pharmaceutical Association that the regulatory process is sufficiently broken that individual procedural and criteria changes will only result in the continued deterioration of the overall capacity of the system to provide timely reviews.

We believe it is urgent to address the challenges facing the system with a full scale process improvement initiative that can build sustainable results.

We believe that it is now time to take a hard look at the regulatory process that is used to approve generic drug submissions (ANDS) and post-market Level 1 (SANDS) and Level 2 (NC) changes, and to develop comprehensive solutions to address delays in drug review times.

In essence we think it overdue to:

- Fix the processes that are vital to our public and private success; and
- Equip the people in the system with the skills, knowledge and tools to succeed.

The elements of this approach are outlined on the following pages.

Strategic Objective

In order to drive sustainable change we must define success.

From our industry's perspective, success should be defined as a reasonable time to clear the regulatory hurdles, so that the generic drug companies can effectively plan their product launches in the Canadian health-care market. Therefore, we need a set of Strategic Objectives related to this outcome.

By December 2013, we will strengthen the capacity of the drug review system to meet the quality, efficacy and safety requirements of the regulatory process, within the following timeframes:

- *Abbreviated New Drug Submissions (ANDS)..... Review completed in 225 days.*
- *Supplemental Abbreviated New Drug Submissions (SANDS).. Review completed in 225 days.*
- *Notifiable Changes (NC)..... Review completed in 90 days.*

These Strategic Objectives are stretch targets but we believe they can be attained.

These Strategic Objectives assume:

- The system continues to provide regulatory confidence by assuring the safety, efficacy and quality of drug products; while
- Providing the basis for delivering needed lower priced drugs to the health-care system; and
- Providing more certainty for the industry in order to continue making investments in plant, machinery and people.

It should be underscored that there is no inherent contradiction in speeding up the process while enhancing its integrity.

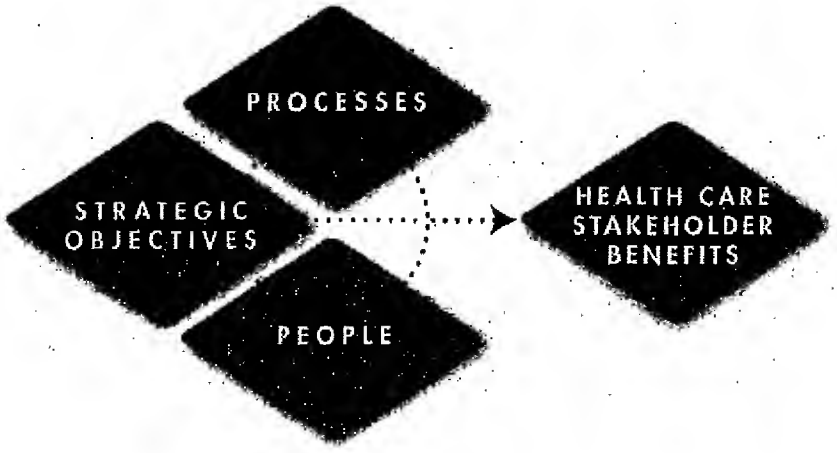
These are our Strategic Objectives. But a first step in this initiative would be to have these Strategic Objectives or alternates confirmed by all of the parties. The Strategic Objectives must have the unambiguous support of the most senior executives from both industry and the federal government. While the Strategic Objectives are ambitious, leaders on both sides need to communicate that they are the right way to proceed.

By providing a description of the required outcome, with a measurement and a timeframe for its realization, all of the parties can focus on the problems and on the solutions that will move the system towards an agreed end state.

Two Primary Areas of Process Improvement

There are two interrelated areas that will need to be the focus of this process improvement initiative: that of process and of people.

By building effective processes and equipping the people we can build a new and improved regulatory system that can deliver sustainable benefits to the department, industry, and the health-care system, including consumers.



Processes

Observers all agree that the current processes are not delivering timely and therefore effective results. It is clear that there is no single fix nor are there a few potential changes that when bundled together would provide anything but symptomatic relief. A robust system that delivers safety, efficacy and quality within a reasonable timeline will require a full scale Process Improvement initiative.

The approach and discipline of Process Improvement will enable Health Canada to rethink how it does its work in order to achieve the new Strategic Objectives.

As managers of generic drug manufacturing firms, we must meet the multiple challenges of producing an increasing quantity of safe, effective and high quality products, while all the while delivering cost savings to the Canadian health-care system. The regulatory system should not be free from simultaneously meeting these same responsibilities.

People

The *Cost-Benefit Analysis: Proposed Fees In Respect of Drugs and Medical Devices Regulations* describe how the government intends to fund the currently under resourced human resources in the drug submissions review and approval functions.

It is incredibly important that people be aligned to the new and improved processes. The people need to have the requisite skills (technical, process and interpersonal), as well as the required knowledge (both technical and industry).

Staffing and skilling up the organization should be done therefore, as part of the overall process improvement initiative during both planning and implementation phases. The human resources funding for the improved process should be determined based upon the new system requirements and the corresponding costs of certain types of human resources.

A Collaborative Approach to the Initiative

We believe that a few principles are essential to the success of this process improvement initiative. These principles are:

- Engaging and sustaining senior leadership in government and industry;
- Delegating accountability for results across all parties; and
- Empowering the key people to achieve results.

Engaging and Sustaining Senior Leadership

Leadership will be the key driver of this process improvement initiative.

We recommend the establishment of a Leadership Group that acts as champions for the respective parties. It is suggested that a corporate executive representing the Generic Industry (as well as a counterpart from the Brand Industry) be included along with the Assistant Deputy Minister, Health Products and Food Branch, Health Canada.

This Leadership Group would be responsible for:

- Setting and promoting the Strategic Objectives;
- Establishing an Industry/Government Working Group to manage the initiative;
- Regularly reviewing progress;
- Deciding on corrective actions as required; and
- Providing reporting back to the respective industries/government on the status of the initiative.

Delegated Accountability – Industry – Government Working Group

This group would have representation from the same organizations but at the level that will permit ongoing decision making in terms of the process improvement ideas, changes and implementation of the changes.

This group must be senior enough to understand the stakeholder, policy and operational considerations, but sufficiently knowledgeable to create the required Improvement Team(s), provide support, review performance and provide feedback to the Improvement Team(s).

It is at the Working Group level that the amount and style of industry participation should be agreed upon. It is recognized that the review process is the government's and there should be no attempt on industry's part to play anything other than a collaborative and supporting role. On the other hand, any new, improved and effective process is likely to be optimal if it has had the active support of the industry partners in the design considerations.

The Working Group must be responsible for building a sustainable solution. **While this document has focused on long-term solutions, that does not alleviate the need, within the approach we have elaborated, to achieve early victories in resolving long-standing issues like the back log of Notifiable Changes.**

Empowering People – Improvement Team(s)

To undertake the scope of changes recommended, it is critical to prepare a team that is sufficiently equipped to undertake a process improvement initiative. The team will need the skills required to undertake the process improvements as well as the technical knowledge to create and sustain a world class drug regulatory review system.

The Improvement Team(s) must have the required resources, recourse to the Working Group as required and the ability to communicate through the Working Group to the Leadership Group. In addition, they must have the ability to engage all of the people that have a stake in the outcome, have knowledge of certain aspects of the implicated processes and can contribute innovative ideas. They need to set in motion focused considerations of what to keep doing, what to stop doing and what to start doing.

The Improvement Team(s) will be responsible for both the design and the implementation of an improved and sustainable drug approvals system.

Appendix B

1. Joint Collaborative Initiative and ANDS Performance (and S/ANDS Performance)

Key Messages:

- The TPD is appreciative of CGPA's offer to help and encourages CGPA to make suggestions as to how they believe the review process can be improved but does not see an advantage to embarking on a collaborative initiative with CGPA.

- Detailed information on "Unique Canadian Requirements" would be appreciated to help us determine what these requirements are and to evaluate their necessity.

- TPD has initiated projects directed at reducing the backlog, many similar to those in the CGPA's proposal, and include an increase in the number of reviewers.

2. Proposal to eliminate the Notifiable Change category of submissions

Key Messages:

- Initial review of the comments received from consultation has lead to revisions of draft Post-Notice of Compliance Changes Quality Document. Once review is complete, the revised document will be shared with industry.

- Health Canada intends to move ahead with the removal of the NC category for Chemistry and Manufacturing change submissions.

- Health Canada is confident that the removal of the NC category will lead to clearer requirments for industry, and make the Department more accountable for meeting review performance timelines.

3. Reports of shortages of some drug products

Key Messages:

- If Health Canada becomes aware of a critical shortage on an important drug, the Department works with manufacturers and the medical community to minimise the impact of the shortage and facilitate access to alternatives.

- As you may be aware, Minister Aglukkaq has written to industry to ensure a collaborative approach on this important issue.

- Health Canada will continue to work with industry, provinces and territories, and the medical community, and act within its power as the drug regulator to reduce the impacts of shortages to the extent possible.

DRUG SHORTAGES: POTENTIAL SOLUTIONS

1) **Notification:**

Voluntary notification of drug shortages to health professionals that is timely, accurate and consistent across industry groups and their membership

2) **Transparency:**

Single window repository for drug shortage notifications that is established and maintained and funded by industry, and is accessible to the public

3) **Patient involvement:**

Patient representation on the multi-stakeholder drug shortages working group that is being coordinated by industry.

4) Strategies to prevent and manage drug shortages:

a. Continued collaboration across the health system to develop best practice guidelines for the prevention and management of drug shortages. This could include options related to:
   - Shortage prevention plans to maintain stable product inventories, or to identify alternate manufacturing options (eg. alternate manufacturing sites, or alternate sources of API)
   - Notification procedures for reestablishment of the supply
   - Early identification of medically necessary products through risk assessment plans
   - Pharmacy/hospital procurement practices to increase diversity in the supply chain
   - Communication strategies for notification and management of shortages
   - Wholesaler, buying group, hospital or community re-allocation strategies to prioritize distribution of product to patients who would be most impacted by supply interruptions
   - Identification of alternatives and risk management practices to minimize harms with treatment switches
   - Managing drug shortages in the health care system at a community and hospital level

b. Expand the shortage notification platform to be a comprehensive resource on drug shortages with:
   - best practice guidelines
   - information developed pursuant to best practice guidelines
   - information for consumers on how to report shortages and when to consult a health professional and in support of the best practice guideline.

SHORTAGES: DRAFTING INSTRUCTIONS

Policy Objective:

The objective of the regulatory proposal is to ensure that notice of drug shortages is provided by manufacturers as early as possible so that decision makers such as health care providers such as physicians and pharmacists, and consumers can respond appropriately.

Instructions:

1. **Requirement to notify**

Create a requirement for manufacturers to notify health professionals, as soon as practicable, of drug shortages.

A drug shortage is considered:

- a temporary interruption in the supply of a medically necessary drug manufactured by an individual manufacturer
- such that the supply of all clinically interchangeable versions is inadequate to meet the current or projected demand at a user level
- as determined by average historic demand

Medically necessary drug is considered:

- Drug used to treat a serious or life-threatening condition
- There is no other adequately available drug as judged by medical staff to be an appropriate substitute

2. **Content of Notification:**

Notification shall (amongst other things) include the following:

- Presentations on the market and presentations that are or will be in shortage
- Reason for the shortage
- Anticipated date for resolving the shortage
- Any information that can be provided to consumers to mitigate the impact of the shortage including clinical information to support a safe transition and potential alternatives

3. **Transparency:**

Create a requirement for manufacturers to establish a (website) that will provide a single window portal for notification of drug shortages to health professionals.

Drug Shortages:
Tool Kit

The Branch's discretionary roles in responding to drug shortages include:

1. **Submission advice & expedited review:**
   - New product (NDS or ANDS)
   - Manufacturing process change for existing supply (SNDS or NC)
   - Site changes for existing supply (EL)
   - Expedited review for any of the above

2. **Access to (Canadian) unapproved alternatives:**
   - Special access programme (external inquiry – pharmacist/health professional)
   - Special access programme (internal inquiry – Office of Risk Management or Inspectorate flags heads-up to SAP) – typically considered as part of a risk mitigation strategy under review by HPFBI , ORM or BGTD
   - Our role involves verification of shortage, consideration of new drug to program, consideration/processing of requests, small role in 'mediating' between health professionals and manufacturers, risk communication (providing input to industry communication)

3. **Risk Management Activities:**

   - Branch risk management activities generally include two elements: **risk assessment** (assessment of violative products for potential health impacts) and **risk mitigation** (strategies that are needed in light of assessment).
   - supply considerations are generally not considered during the risk assessment process
   - supply considerations are included when assessing the potential impacts of risk mitigation strategies.
   - risk assessments are used when considering measures, such as issuance of a license or the listing of a foreign site on a license in the absence of full compliance, to support access to medically necessary products.

2010-10-15

SESSION 1 / DAY 1

TOPIC B: ACCESS ISSUES – *SPECIAL ACCESS, DRUG SHORTAGES AND DRUG DISCONTINUANCES*

OVERVIEW AND STATEMENT OF OBJECTIVE

The objective of this document is to provide for purposes of discussion a model regarding special or exceptional access to drugs for human use, and possibly medical devices, outside of enrolment in clinical trials to support a market authorization or sales pursuant to a general market authorization. It also includes a model for notification regarding requirements for drug shortages and discontinuances.

Currently, exceptional access involves requests from physicians for access to products that are not available in Canada, for patients with a serious or life-threatening condition when alternatives have failed or are not available. The regulatory authority to permit access is discretionary and decisions to authorize or deny requests are made on a case-by-case basis by taking into consideration the nature of the medical emergency, the availability of marketed alternatives and the information provided in support of the request regarding the use, safety and efficacy of the drug. If access is granted, the practitioner agrees to report on the use of the drug including any adverse events encountered with such use and, upon request, account for all quantities received.

Requests for exceptional access are submitted by individual physicians on a named patient basis, or in anticipation of future patient needs. For many drugs, the number of requests received and authorized annually is quite small. For others, the demand for exceptional access becomes routine and can involve hundreds of patients each year for several years. While the population receiving unapproved drugs on an exceptional basis can sometimes compare to or exceed a large scale clinical trial, the application and reporting requirements remain a very transactional process between Health Canada and a practitioner. The framework does not approach population level access in a population based manner.

Products requested through this mechanism include pharmaceuticals, biologics, radiopharmaceuticals and natural health products that can not otherwise be sold in Canada. Many of these products can not otherwise be sold in Canada because they have not undergone a regulatory review for a market authorization; others are marketed products that were removed from the market following compliance action; drugs that are in shortage or have been discontinued; or drugs that received a negative decision following regulatory review.

The current framework demonstrates that the range of products requested on an exceptional basis is quite broad, as are the needs for seeking such access. A future model for exceptional access must balance these access needs with patient safety, and must approach population level access with population appropriate requirements and

considerations. The model must not discourage participation in clinical trials or interfere with the normal path of product development.

The model will include application requirements for exceptional access to non-marketed drugs. The application requirements will permit Health Canada to determine whether the potential benefits outweigh the potential risks. The amount and type of information required to demonstrate this will depend on the type of product, its intended use, and the existing level of knowledge and experience with the product. As such, application requirements will be different for exceptional access applications for individual patients, medium size patient populations and large size patient populations.

Determination of whether exceptional access is appropriate is an important element of the model. Applicants will be required to demonstrate that the patients for which exceptional access is requested have a serious or life-threatening condition, and other appropriate treatments do not exist or have failed. They must also be able to demonstrate that exceptional access is for treatment, diagnosis or monitoring purposes and will not discourage participation in clinical trials or interfere with product development.

RELEVANT LEGISLATIVE PROPOSALS FROM BILL C-51

12. (1) No person shall advertise, sell or import for sale a therapeutic product that does not have a market authorization or is not a designated therapeutic product.

(2) A person does not contravene subsection (1) if

(a) they are the holder of a clinical trial authorization and the advertising, selling or importing is for the purpose of a clinical trial to which the authorization relates; or

(b) they sell the therapeutic product to a person who is the holder of a clinical trial authorization or they import it for sale to that person.

18.7 (1) Subject to the regulations, the Minister may, on application, issue a market authorization to a person in respect of a therapeutic product other than a designated therapeutic product if the Minister is of the opinion that the person has established that the benefits that are associated with the therapeutic product outweigh the risks.

(2) The market authorization is deemed to be subject to the terms and conditions that are prescribed from time to time.

(3) The Minister may issue the market authorization subject to the additional terms and conditions that he or she considers appropriate.

(4) The holder of the market authorization shall comply with the terms and conditions to which the authorization is subject.

30. (1) The Governor in Council may make regulations for carrying the purposes and provisions of this Act into effect, including regulations…

(b) defining, in respect of a food, therapeutic product or cosmetic or a class of foods, therapeutic products or cosmetics, "collect", "manufacture", "prepare", "prescription", "preserve", "process", "product monograph", "test" or "wholesale"

(h) respecting
(i) the labelling, packaging or advertising — or the offering or exposing for sale — of foods, therapeutic products or cosmetics,
(ii) the size, dimensions or fill of, or other specifications for, packages of foods, therapeutic products or cosmetics,
(iii) the sale or the conditions of sale of a food, therapeutic product or cosmetic, or
(iv) the use of a substance as an ingredient in a food, therapeutic product or cosmetic

(s) specifying the terms and conditions to which registrations or licences referred to in section 18.1, clinical trial authorizations, market authorizations or establishment licences are subject

(x) establishing classes of clinical trial authorizations, market authorizations or establishment licences and specifying the class or classes of therapeutic products to which each class relates

(y) respecting applications for or the issuance, amendment, suspension, revocation or transfer of clinical trial authorizations, market authorizations or establishment licences

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MOCK FRAMEWORK FOR DISCUSSION

EXCEPTIONAL ACCESS

1) Application Requirements

- Applications for exceptional access can be filed by a practitioner or manufacturer.
- The application requirements for exceptional access will be different for small (individual patient), medium and large size patient populations.
- All applications for exceptional access must include:

Basic information:
- The names of the drug
- The name of the applicant and their contact information

Chemistry and Manufacturing:

- Chemistry and manufacturing information adequate to ensure the proper identification, quality, purity and strength of the product
- A description of the facility where the product is manufactured, including the GMP status

Use Information:

- Indication for the intended use of the drug
- Rationale for the intended use of the drug, including information on the therapeutic options and reason why the non-marketed product is the best choice
- Criteria for patient selection
- The method of administration of drug, dose and duration of therapy
- Information to demonstrate that the patient(s) is not eligible to participate in a clinical trial for the drug

Benefit-Risk Information

- Pharmacological and toxicological information to conclude the drug is reasonably safe at the dose and duration proposed for exceptional access. This information should be adequate to support a clinical trial of the same population size that is to be treated by exceptional access
- A description of the clinical procedures, laboratory tests or other monitoring necessary to monitor the effects of the drug and minimize risks
- A copy of the product information that will be provided with the drug, including information on the benefits and risks of the drug, and the clinical procedures and tests that should be undertaken to minimize the risks of the drug
- A copy of the information, as it will be provided in the consent form, to inform patients of the risks and anticipated benefits to their health as a result of receiving the drug

- For medium and large size patient populations the application must also include:

Use information

- A description of the patient population to be treated
- A statement of the development status of the drug for the exceptional use indication. If a product is not being developed for the exceptional use indication, the statement must include the reasons why the product is not being developed.
- For large populations, the statement of the development status must demonstrate that the manufacturer intends to file for a market authorization; and the product is being investigated in controlled clinical trials to support a market authorization, or that all clinical trials have been completed

Benefit-Risk Information

- Clinical evidence of the safety and efficacy of the drug to justify a clinical trial of the same population size as expected with exceptional access

2) Authorization

- Criteria for authorization may be different for small, medium and large size patient populations, and will be based on the information required in the application.

- In general, authorization for exceptional access will be based on an assessment of potential benefits and potential risks. This will depend on the type of product, its intended use, and the existing level of knowledge and experience with the product.

- For all levels of access, Health Canada must be of the opinion that:
  - Exceptional access will be limited to patients who have a serious or life-threatening condition, and that appropriate alternatives do not exist or have failed
  - Providing the drug for exceptional access will not interfere with drug development, including the clinical trials that could support an application for market authorization
  - There is sufficient pharmacological/toxicological or clinical data to support a comparably sized clinical trial of the same population that is expected with exceptional access

- Authorizations may be limited to a specified amount of drug or duration of treatment.

- Authorizations will be limited to the intended size of the patient population identified in the application. If a significant number of individual patient applications are submitted or there is increase in enrolment in the medium size exceptional access, Health Canada can request that the authorization holder submit an application for medium or large size patient population.

3) Conditions of authorization

- Practitioners receiving drug pursuant to an exceptional access authorization will be required to report to the authorization holder on the use of the drug including any adverse events. The reporting requirements for adverse event will be consistent with expedited reporting requirements for clinical trials.

- Authorization holders will be required to report adverse events to Health Canada. The reporting requirements will be consistent with the expedited reporting requirements for clinical trials.

- Authorization holders will be required to submit an annual report for all exceptional access use that continue for 1 year or longer.

- The annual report must include:
  - Information on the number of patients treated;
  - The outcomes of treatment, including any adverse events; and
  - An update on the development status of the product for the exceptional access uses, including the status of any clinical trial that are ongoing or planned to support a market authorization

- For exceptional access that does not continue for 1 year or longer, including individual patient access, the applicant must report at the time of closing the exceptional access use. The report must include the results of the exceptional access use, including any adverse effects.

DRUG DISCONTINUATION

1) Notification

- Market authorization holders will be required to notify Health Canada 6 months in advance of discontinuing manufacturing of a drug when it has a public health impact. This will include single source drugs that are used to treat a serious or life-threatening condition.

- Notification shall include the following:
  - Company name and contact
  - Presentations available and discontinued
  - Anticipated date of discontinuation

- Market authorization holders will be required to supply, on request, all data relating to volume of sales and if available, the volume of prescriptions.

- Market authorizations holders will be required to provide, on request, a risk assessment of product uses, potential alternatives and other potential sources of the drug.

2) Reduction of notification period

- Market authorization holders will be able to request a reduction of the notification requirement on an exceptional basis. The requests must include a justification for not providing the normal notification period.

- Accepted reasons for potentially granting a reduction will be identified in guidance.

3) Disclosure of notified Discontinuations

- Health Canada will make available information regarding product discontinuations in the therapeutic product register.

DRUG SHORTAGES

1) Notification

- Market authorization holders will be required to notify Health Canada of anticipated or occurring drug shortages when it has a public health impact. This will include single source drugs that are used to treat a serious or life-threatening condition.

- Notification shall include the following:
  - Company name and contact
  - Presentations on the market and presentations that are or will be in shortage
  - Anticipated date for resolving the shortage
  - Any information that can be provided to consumers to mitigate the impact of the shortage including clinical information to support a safe transition and potential alternatives

2) Disclosure of notified Shortages

- The Minister will make available information regarding product shortages in the therapeutic product register.

APPENDIX A

INTERNATIONAL FRAMEWORKS

UNITED STATES

- The regulations for expanded access to investigational drugs for treatment:

  Title 21 CFR Parts 312 and 316

  http://www.access.gpo.gov/nara/cfr/waisidx_98/21cfr312_98.html

  http://www.access.gpo.gov/nara/cfr/waisidx_98/21cfr316_98.html

- The regulations for advance notice of drug discontinuations:

  Title 21 CFR 314.81(b)(3)(iii)

  http://www.access.gpo.gov/nara/cfr/waisidx_98/21cfr314_98.html

EUROPEAN UNION

- Requirement to notify regulatory authorities when market access to a product will be temporarily or permanently interrupted:

  Directive 2001/83/EC, Article 23a

  http://ec.europa.eu/health/documents/eudralex/vol-1/index_en.htm

- Requirement for market authorization holders to maintain appropriate and continued supplies of products:

  Directive 2001/83/EC, Article 81

  http://www.access.gpo.gov/nara/cfr/waisidx_98/21cfr316_98.html

- Authority for member states to make medicinal products available for compassionate use:

  Directive 2001/83/EC, Article 5
  Regulation EC/726/2004, Article 83

  http://www.access.gpo.gov/nara/cfr/waisidx_98/21cfr316_98.html

Jurisdiction	Program
United States	• CDER Drug Shortage Program (DSP) established to address potential or actual drug shortages of Rx, OTC or generic drugs that have significant impact on public health. • There are no regulatory requirements for manufacturers to report drug shortages. FDA participates in managing drug shortages through discretionary use of regulatory options (see below). • Focus on medically necessary products (serious or life-threatening disease, not other available source or alternative) • DSP maintains a website and email subscriber list to share information provided by manufacturers on drug shortages. • DSP can also: – Expedite review of submissions from manufacturers – these submissions may be in support of a marketing application for a new product (NDA or ANDA), or may be in support of manufacturing changes which will allow a product to be available (for example, a chemistry supplement for a new manufacturing site) or may involve other issues (for example, toxicity data for an impurity identified in a product) – Identify alternate manufacturers that can initiate or ramp-up production – Find new/additional sources of raw material – Advise/consult with sponsors on resolution of manufacturing issues – Allow temporary import of a non-US product, in rare instances • FDA and TGA Cooperative agreement – p8 (for FDA). "FDA will endeavour to provide assistance to TGA when drug shortage situations involving medically necessary human pharmaceuticals occur in Australia by providing information regarding manufacturers of these pharmaceuticals to or in the United States and the regulatory status of these manufacturers when possible."
Australia	• No regulatory requirements to notify of drug shortages. Request by agency that sponsors notify the TGA of shortages that could disadvantage patients. • Authority under section 19A of the *Therapeutic Goods Act* to grant temporary approval to a drug that could substitute for the goods that are unavailable or are in short supply. • FDA and TGA Cooperative agreement – p8 (for TGA).TGA will endeavour to provide assistance to FDA when drug shortage situations involving medically necessary human pharmaceuticals occur in the U.S. by providing information regarding manufacturers of these pharmaceuticals to or in Australia and the regulatory status of these manufacturers when possible.
United Kingdom	• The Department of Health has Best Practice Guidelines (*Notification and management of medicines shortages, 2006)* that were prepared in partnership with generic manufacturers. • Article 23a and 81 (Directive 2001/83/EC) requires marketing authorization holders to 1) maintain appropriate and continued supplies of products, and 2) to notify the licensing authority of a product ceases to be available on the market either temporarily or permanently. The legislation requires notification to the licensing authority 2 months before the interruption, in all but exceptional circumstances.

	• The guidelines recommend notification to DH (not MHRA) if a shortage is likely to impact on patient care. • If a shortage is reported, the DH and company work together to come to an agreement on the criticality of the product, and to develop strategies for dealing with the shortage.
European Union	• Article 23a and 81 (Directive 2001/83/EC) requires marketing authorization holders to maintain appropriate and continued supplies of products, and to notify the authority of a product ceases to be available on the market either temporarily or permanently. The legislation requires notification to the licensing authority 2 months before the interruption, in all but exceptional circumstances.

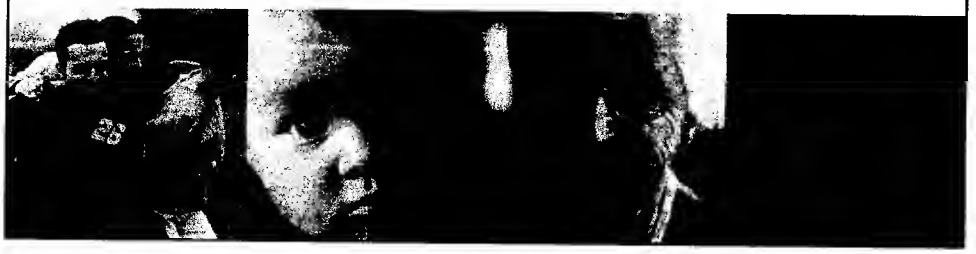
Health Canada / Santé Canada

Helping the people of Canada maintain and improve their health

Aider les Canadiens et les Canadiennes à améliorer leur état de santé

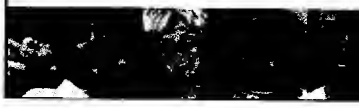
Drug Shortages and Discontinuances

FPT AIDS Committee & STBBI Issue Group
November 17, 2010



Introduction

- Office of Legislative and Regulatory Modernization, HPFB
- Responsible for developing proposals to modernize legislation and regulations for food and drugs
- Key initiatives:
  - Bill C51: Legislative proposals to amend the *Food and Drugs Act*
  - Modernization of *Food and Drug Regulations*
  - Access Issues related to drug shortages, drug discontinuances, product withdrawals and orphan drugs



Shortages in the news…

thestar.com

Back to Drug shortages trouble pharmacists

Drug shortages trouble pharmacists

November 14, 2010

Rob Ferguson

There are shortages of some prescription drugs — including tetracycline and some anti-nausea r forcing pharmacists to scramble to meet patients' needs, industry sources say.

The trouble lies with supply shortages, such as difficulties for some manufacturers in getting the creating a domino effect in which demand for similar drugs is going up and leading to sellouts.

CMAJ Medical knowledge that matters

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Current

Past

NEWS

November 1, 2010

Continuing drug shortages affect North American patients

Pharmacists across Canada say drug shortages are affecting patients and will likely conti so, despite assurances from manufacturers that they are trying to increase supplies.

"There is a problem, and it is significant," says Jeff Morrison, director of government relat the Canadian Pharmacists Association.

Access Issues WG

- In recent years, Health Canada has become aware of a number of drug shortages and discontinuations.
- In January 2010, Health Canada established a working group to explore access issues related to shortages, discontinuations, withdrawals and rare diseases
- For shortages and discontinuations, role of the group is to:
  - develop a better understanding of the impact of supply interruptions
  - explore the Department's role in monitoring or responding to drug supply interruptions in our capacity as a regulator.

Our experience

- In most cases, supply interruptions are unfortunate but manageable issues that are handled by industry with minimal involvement from Health Canada.
- A small portion will result in unmet medical need where patients have no suitable alternative on the CDN market.
- These can involve serious and non-serious medical conditions
- Common complaints or issues:
  - Unclear roles and responsibilities
  - Lack of notification and communication
  - Absence of identified alternatives

General Principles

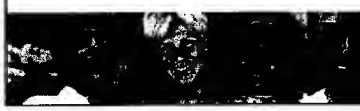
- Supply interruptions have a public health impact
- Access to health products involves industry, health professionals, government and patients
- Supply management and prevention are primarily an industry responsibility
- Health Canada will continue to have a role in responding to drug shortages and discontinuations
- This involvement will primarily be limited to :
  - shortages involving medically necessary drugs (i.e.: serious/life-threatening condition, no alternative) and;
  - shortages that can not otherwise be managed in the marketplace

Recent Activity

- The work on supply interruptions is being explored within the context of regulatory modernization of the *Food and Drug Regulations*.
- Options that have been explored:
  - Notification requirements for drug shortages
  - Notification requirements for drug discontinuations
  - Authority for Health Canada to share information received from notifications with public, via a Health Canada database on therapeutic products

Recent Activity

- Paper on Access Issues presented at recent Technical Discussions on Regulatory Modernization.
- Participants included industry regulatory affairs professionals, Health Canada, PHAC, patient and consumer groups, health professionals, academics and FPT drug plan managers
- Canadian Pharmacists Association recently initiated a membership poll to learn more about the extent of shortages and their impact on patients



Next Steps

- Analyze feedback received from Technical Discussions and identify areas needing further policy work
- Develop regulatory proposals to support notification and communication of drug shortages
- Continue to work with health professional associations and industry to clarify and communication roles and responsibilities

Monday, 2011-01-10

s.21(1)(a)
s.21(1)(b)
s.21(1)(d)

DRUG SHORTAGES

ISSUE:

- Drug shortages are temporary supply interruptions that can have a public health impact. They can arise from a variety of different causes including manufacturing problems, shortages of raw materials, disruptions in the supply chain, and regulatory decisions related to safety, efficacy or quality of a product.

- In most cases drug shortages are unfortunate but manageable issues that are handled by industry with minimal involvement from Health Canada. A small portion of drug shortages result in treatment interruptions for patients.

- As a regulator, Health Canada is responsible for ensuring that products sold on the Canadian market meet high standards with respect to safety, efficacy and quality. In the past, when Health Canada has been advised of a shortage, the Department has worked with manufacturers, where possible, to minimize the impact of shortages and to make sure that information about shortages is made available to those who need it.

- There are currently no regulatory requirements related to shortage prevention, supply management, shortage notification or communication. Manufacturers are required to notify Health Canada within 30 days of discontinuing sales of drug.

CONSIDERATIONS AND OPTIONS:

1. There is often an expectation from health professionals and patients for Health Canada to resolve drug shortages. While the Department can play a role in responding to drug shortages, shortage prevention and management are primarily industry responsibilities.

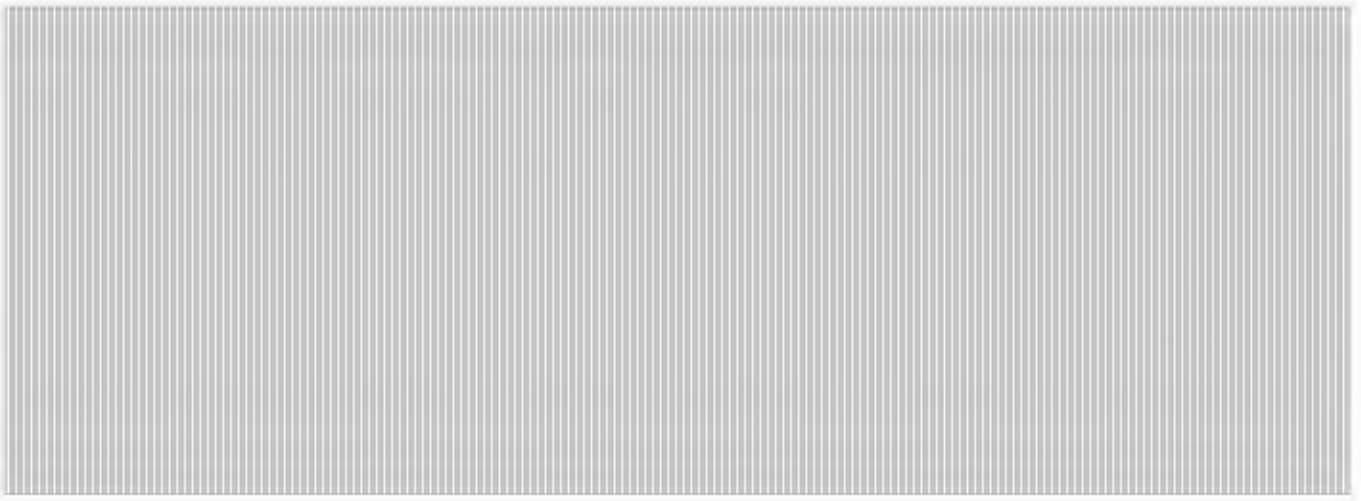
   It is recommended that the Department encourage industry to develop best practices for shortage prevention, management and communication.

   It is also recommended that the Department develop a fact sheet for the Health Canada website outlining the Department's role as a regulator in responding to drug shortages.

2. A primary complaint of health professionals is the absence of timely, accessible and consistent notification of potential or occurring drug shortages. In October 2010, Health Canada's Office of Legislative and Regulatory Modernization presented a discussion paper on access issues related to drug shortages at the Technical Discussions on Regulatory Modernization. The paper proposed mandatory notification by manufacturers of potential or occurring drug shortages. Analysis of the feedback received on the proposal is currently underway [redacted]

s.21(1)(a)
s.21(1)(b)
s.21(1)(d)

Monday, 2011-01-10



NOTIFICATION OF DRUG SHORTAGES

Issue: The objective of a notification scheme for drug shortages would be to provide health care providers and patients with information to support decision-making in the management of drug shortages. Two options for notification (voluntary or mandatory) are under consideration to meet this objective.

	VOLUNTARY NOTIFICATION	MANDATORY NOTIFICATION
Proposal	Reports of drug shortages would be submitted to Health Canada on a voluntary basis by manufacturers, and health professionals. Reports would be published on a website and distributed by email list server.	Market authorization holders would be required as a condition of authorization to notify Health Canada of anticipated drug shortages. Reports would be published on a website and distributed by email list server.
UNIQUE ELEMENTS		
Reporting requirements	Recommendations for reporting (definition, content, timing, scope) would be established in guidance. Companies would not be obligated to follow. We may receive information that is not helpful for end users in managing the shortage.	Reporting requirements would have to be established in regulation. There are not well established definitions of drug shortage. Need to set the requirements and the triggers "within reach" of manufacturers but that is still sensitive to potential supply interruptions.
Compliance and Enforcement	As a voluntary system, there is no mechanism to address companies who fail to notify. Therefore, susceptible to bad company behaviour.	Needs a compliance and enforcement strategy for companies who fail to meet the requirements. Under current legislation, without injunction powers and non-significant fines, there are

		limited tools for dealing with chronic or blatant non-compliance.
COMMON ELEMENTS		
Roles and Responsibilities	Establishes a role for Health Canada in responding to drug shortages: – Could create pressure for more involvement beyond our capacity as a regulator; – Also provides an opportunity to show leadership on this issue and more clearly establish what is and what is not our responsibility as the regulator	
Operational (Staff and IT)	Need an identified operational area with dedicated staff to receive and process notifications Need to establish a website and an email list server for posting and disseminating notifications. Need web support to ensure notifications are publicly available on an expedited basis and to a consistent service standard.	

Health Canada / Santé Canada
Deputy Minister / Sous-ministre
Ottawa, Canada
K1A 0K9

FOR CONCURRENCE

Our file / Notre référence
11-103145-864

MEMORANDUM TO THE MINISTER OF HEALTH

s.21(1)(b)
s.21(1)(c)

Letter to pharmaceutical industry associations soliciting information on drug shortages

SUMMARY

- Your office requested a letter from you to relevant industry associations seeking their co-operation in the voluntary provision of information on drug shortages.
- The attached letter is addressed to senior representatives at the Canadian Generic Pharmaceutical Association (CGPA), Canada's Research-Based Pharmaceutical Companies (Rx&D), and BIOTECanada.
- The letter (Appendix A) formally requests that associations provide information on drug shortages, either voluntarily or potentially through regulatory measures, based on a set of criteria to be developed with them and others.
- Provincial / Territorial (P/T) officials have been advised of the intention to send a letter to industry representatives.

BACKGROUND:

The Canadian Pharmacists Association (CPhA) published a report on December 15, 2010 which claimed that Canadian pharmacists were experiencing an increase in drug shortages. Recently, there have been media reports in Canada (and the US) on drug shortages. The majority of this coverage has been driven by the impact on health professionals, particularly pharmacists. It is unclear whether drug shortages are adversely affecting significant numbers of patients.

Departmental officials have engaged in informal discussions with stakeholders to gain a broader understanding of the issue and The Canadian Agency for Drugs and Technologies in Health (CADTH) is completing an environmental scan of drug shortages.

.../2

s.21(1)(a)
s.21(1)(b)

At the request of your office, we have prepared a draft letter which requests that industry association members provide information on drug shortages.

CONSIDERATIONS:

The letter (Appendix A) formally requests that association members voluntarily provide information on drug shortages based on terms to be developed. It also raises the possibility of a mandatory approach through regulation should industry members reject the proposal for a voluntary approach.

It acknowledges that stakeholders will be engaged in further discussions. This recognizes that any effective long term solutions would require the active involvement of provinces and territories as well as the provider communities.

we have apprised P/T drug plan managers of the possibility of your communication to drug industry associations.

OPTIONS AND RATIONALE:

The following letter proposes a process which involves stakeholders in determining the most appropriate methods of collecting and disseminating information on drug shortages.

s.14(a)

The CPhA has indicated willingness to convene a meeting of key stakeholders.

It is proposed that you copy your P/T colleagues on this letter. Health Canada officials will engage P/T officials in any follow-up discussions.

.../3

Should you decline to sign the attached letter, your officials will continue to explore options available to the federal government.

RECOMMENDATIONS:

It is recommended that you sign the letter which requests that industry association members provide information on drug shortages.

APPROVED BY

Deputy Minister

I concur: X

I do not concur: ____

Minister

MAR 1 1 2011

Date

MECS# 11-103145-864

Contact: Abby Hoffman, A/ADM, SPB
Telephone: 946-1791

Attachment:
Appendix A - Letter requesting information on drug shortages.

Document created on:1 March 2011

Minister of Health | Ministre de la Santé

Ottawa, Canada K1A 0K9

MAR 1 1 2011

Mr. Jim Keon
President
The Canadian Generic Pharmaceutical Association
409-4120 Yonge Street
Toronto, Ontario M2P 2B8

Mr. Russell Williams
President
Rx&D
1220-55 Metcalfe Street
Ottawa, Ontario K1P 6L5

Mr. Peter Brenders
President and Chief Executive Officer
BIOTECanada
600-1 Nicholas Street
Ottawa, Ontario K1N 7B7

Dear Messrs. Keon, Williams and Brenders:

I am writing to solicit your collaboration on the issue of drug shortages. While the precise extent of drug shortages in Canada is unknown, reports from providers and patients suggest that shortages are occurring more frequently, may be more difficult to resolve and have the potential to adversely affect patient care.

Many factors may contribute to a shortage of a particular drug product, and various players may be involved in mitigating the situation. However, your members are positioned to advise on current or impending shortages and to provide information about the anticipated duration of any problem.

During recent discussions on the modernization of the *Food and Drug Regulations*, your respective associations indicated support in principle for the idea of a notification requirement for drug shortages albeit with some concerns (e.g. definition and confidentiality). I am pleased that your associations understood and supported, in principle, the policy objective of providing information to those that are impacted and/or are in a position to mitigate these shortage situations.

.../2

Canada

Consequently, I would appreciate it if your members would voluntarily provide information on drug shortages. Information would be disclosed based upon a set of criteria to be established by key stakeholders, including your organizations and members. In the event this option is not viable, we will consider regulatory alternatives. However, I would prefer, based on your understanding and support, that a voluntary approach be pursued.

I look forward to hearing from you. I will ask my officials to follow-up with you to confirm your members' willingness to provide the required information and to set up further discussions among key stakeholders on potential next steps.

Sincerely,

Leona Aglukkaq

c.c. Provincial/Territorial Ministers of Health
Canadian Pharmacists Association
Canadian Hospital Pharmacists Association

Page(s) 000080 to\à 000095

Is(are) under consultation

DRUG SHORTAGES

MAPPING SUPPLY CHAIN

Santé Canada Health Canada

Presented to Joanne Garrah
Associate Director
Office of Legislative and Regulatory Modernization
Health Canada

14 July 2011

SECOR

MONTREAL :: NEW YORK :: PARIS :: QUEBEC :: TOR(

SUMMARY OF FINDINGS

Shortages affecting commonly used drugs are becoming frequent with Canadian pharmacies being affected on a weekly basis. Health Canada asked SECOR to assist in gathering information on why drug shortages occur and how best practices could mitigate or diminish the impact of supply interruptions.

CONTEXT

Canada does not track drug shortages at a national level. Nevertheless, since the pharmaceutical supply chain is global in reach, any shortages identified elsewhere are likely to percolate through to Canada. The US reported a tripling of drug shortages between 2005 and 2010. Many of the products in short supply were sterile injectables. Manufacturing failures related to product quality were the main cause of disruption. Sterile drugs are usually made in large batches. Since contamination could be fatal for a patient, a large batch may be destroyed when contamination occurs, creating a potential shortage.

Consolidation of both the brand and generic industries has created larger but fewer manufacturers supplying a given drug which exacerbates the impact of manufacturing failures. In some instances, only a single manufacturer may producing a key ingredient or be responsible for a key processing step. When failures occur, alternate suppliers cannot rapidly fill demand. Manufacturing is highly regulated. Developing a manufacturing process and having it approved and licensed by regulators can take between two and three years even for generic products. In situations where a firm already has a license to produce a given drug, setting up a manufacturing run and finding raw ingredients can take weeks or months.

A study by the Canadian Pharmacists Association reveals that more than 93.7% of pharmacists have trouble in filling approximately 10 prescriptions per week due to drug shortages. Among the top ten drug shortages mentioned by pharmacists, many were common antibiotics and anti-hypertensives. Furthermore, many pharmacists are not notified of a drug shortage until supplies are close to exhaustion. Supply disruptions for generic drugs are more prominent than for brands.

Drug shortages create chain reactions with multiple stakeholders being affected. They predominantly occur at the manufacturing stage creating:

- A knock-on drug shortage where remaining suppliers come under strain when one supplier fails
- Anxiety for the patient as regular therapy becomes scarce or unavailable
- Additional pressure on healthcare resources, which has been estimated in the US at around $216M per year. This pressure arises from:
  - Time consumed by healthcare professionals locating residual stock or finding suitable therapeutic alternatives
  - Delays in treatment due to due to lack of suitable alternatives or requirement for education on alternative therapies
  - Worse health outcomes due to unscheduled therapy switching, treatment delays or errors
  - Price increases on existing stock as suppliers/distributors try to ration supplies/

POINTS OF DISRUPTION

Drug shortages can occur at any point in the supply chain. However, most occur at the manufacturing stage and include:

- Shortages in the supply of raw or active ingredients, which are mostly sourced in China and India;
- Quality issues with active ingredients, a good example being heparin
- Issues in compliance when there are changes in regulations abroad;
- Delay in obtaining regulatory approval when a manufacturing process changes;
- Issues in manufacturing that affect the product quality such as contamination
- Discontinuation of drugs that are no longer economically viable; and
- Limited manufacturing capacity.

Other minor changes in the supply chain that can exacerbate problems at the manufacturing stage include:

- Change in demand due to disease outbreaks or changes in prescribing practices; and
- Product withdrawals.

POTENTIAL OPPORTUNITIES FOR REMEDIAL ACTION

Canadian stakeholders can mitigate or diminish the impact of drug shortages by modifying current practices. The US and UK, as well as some independent Canadian organizations already have good practice in place. Canada requires a national, concerted effort by all stakeholders to tackle the drug shortage problem. Possible risk mitigation strategies include:

- Requiring manufacturers to notify authorities when supply disruptions are likely to occur;
- Tracking and publishing disruptions on a web site;
- Speeding up regulatory approvals for changes to the manufacturing processes;
- Warning alternate suppliers when a disruption notification is received;
- Providing a list of therapeutic alternatives and warning suppliers of potential increases in demand;
- Monitoring foreign regulatory agencies for major changes in their regulations that may impact Canadian supply;
- Helping locate foreign manufacturers that could temporarily fill a shortage while problems with the usual manufacturer are rectified; and
- Using a pharmacy support program that allows pharmacists to locate residual supply in the system rapidly.

Page(s) 000099 to\à 000103

Is(are) under consultation

Santé Canada | Health Canada

Drug shortages

Mapping supply chain challenges

SECOR

Final version for comment

July 20, 2011

000104

Drug shortages are becoming an important concern in Canada

Santé Canada Health Canada

Health Canada wants to

- Characterize the nature of the problem
- Identify best practices in dealing with drug shortages

Health Canada asked SECOR to assist in gathering information

In this mandate, SECOR has:

1. Mapped drug supply chains for branded small-molecule drugs, generics and biologics
2. Identified points of failure in each of the supply chains for these products
3. Identified best practices to mitigate or diminish the impact of supply interruptions

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3.	Drug Shortages	11
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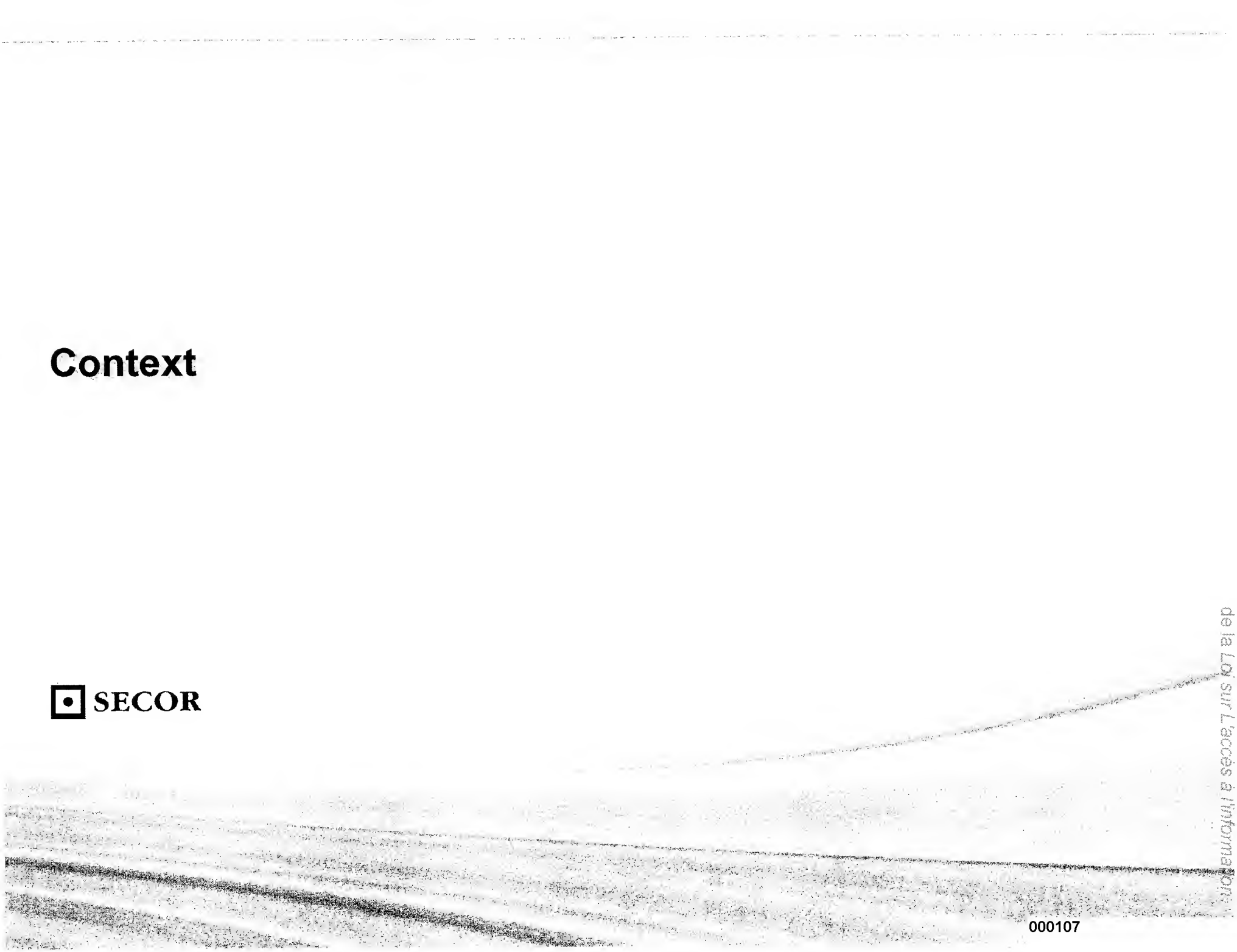
Context

SECOR



Drug supply disruptions are on the rise, especially for sterile injectables

Santé Canada Health Canada

Between 2005 and 2010, the FDA noted a tripling of drug shortages reported by manufacturers[1]

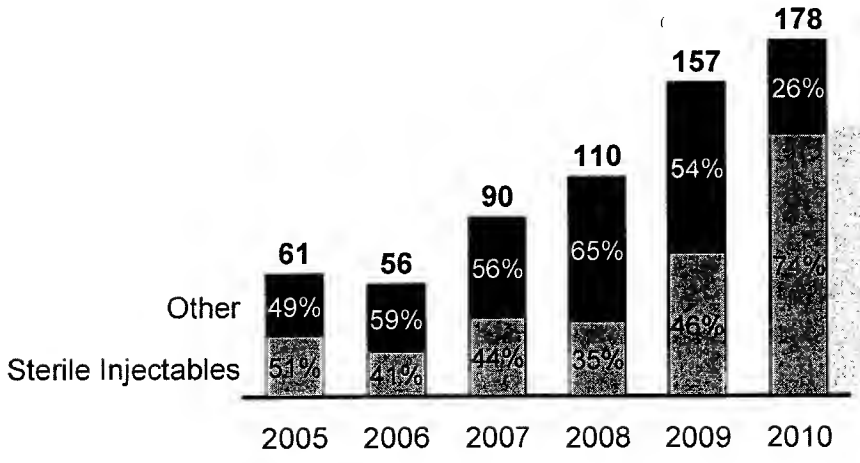
Sterile injectables represent a large proportion of these shortages: 74% in 2010 [1,2]

- Most problems occur in manufacturing [1,2], principally with product quality [3]
  - Sterile manufacturing is complex [4,5] and consolidation within the industry exacerbates the impact of production problems [5]

These drug shortages are rarely categorized as brand vs. generic vs. biologic due to the sensitive nature of this type of classification

- However, a SECOR analysis of current drug shortages listed by the FDA indicates that approximately 90% are related to generics (June 2011) [6]

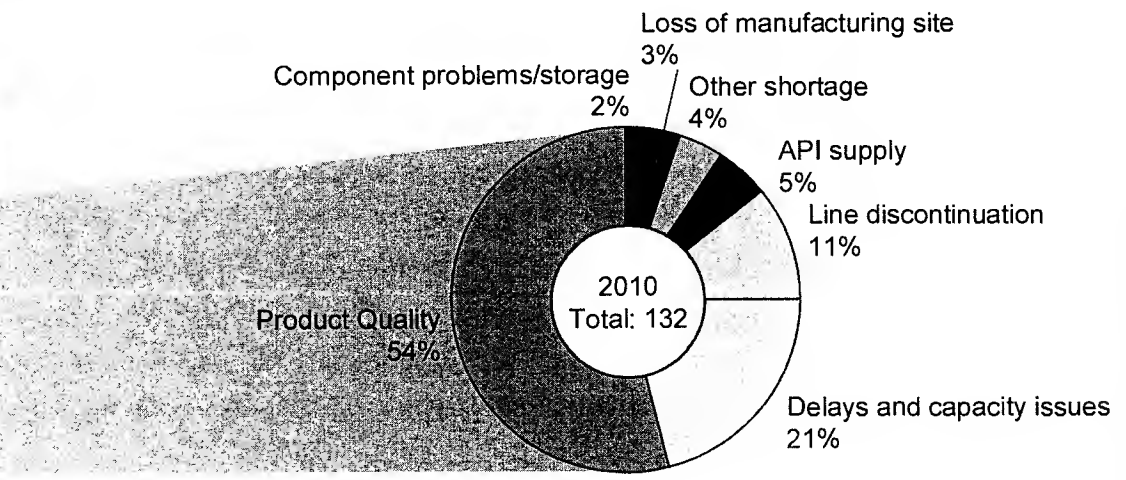
Drug Shortages in the U.S.
Total newly reported drug shortages, percent of total, 2005-2010



Note: excludes vaccines, immune globulin and other biologic products managed by the FDA's Center for Biologics Evaluation and Research

Source: Center for Drug Evaluation and Research, FDA [1,2]

Causes of Drug Shortages in Sterile Injectables in the U.S.
Percent, 2010



Source: Drug Shortages: A Challenge to Patient Safety, presentation by Christina Michalek at the Healthcare Business Summit, Las Vegas April 2011 (original source data: CDER) [2]

Shortages in Canada are frequent and can occur with commonly used drugs

Santé Canada Health Canada

Drug shortages are not officially tracked in Canada. However, SECOR's research and end-user reports suggest that they occur frequently [7,8,9,10]

- The Canadian Pharmacists Association survey reveals that 93.7% of Canadian hospital and retail pharmacists have difficulty filling prescriptions every week due to drug supply issues [7]
  - An average of 10 prescriptions per week cannot be filled without delay due to drug shortages [7]
- The University of Saskatchewan's Drug Information Services currently lists 32 drugs in short supply (June 2011) [8]
  - In 2010, some 15 drugs accounted for 75% of drug shortages identified by the Saskatchewan College of Pharmacists' survey [9]

End-user drug shortages include common drugs such as antibiotics, anti-hypertensives and anesthetics [5,7]

- Of concern is the lack of notification [7] and the absence of therapeutic alternatives for certain drugs [5]
  - Some 30% of pharmacists are never notified of drug shortages [7]
  - Furthermore, only 16% of notifications come from manufacturers [7]
    - The remaining 84% of notifications come from stakeholders further down the supply chain including other pharmacies and pharmacy head offices [7]
  - Certain drugs such as amikacin and acyclovir do not have therapeutic alternatives; [3] shortages have been attributed to patient deaths [11]

Top 10 Drug Shortages 2010 - National: (n=825)

1.	Amitriptyline	(n=164)
2.	Cephalexin	(n=109)
3.	Metoclopramide	(n=54)
4.	Clonidine	(n=45)
5.	Methotrimeprazine	(n=43)
6.	Diltiazem	(n=32)
7.	Tetracycline	(n=30)
8.	Amoxicillin + Clavulanate	(n=28)
9.	Hydralazine	(n=26)
10.	Metronidazole	(n=19)

Source: Canadian Drug Shortages Survey, Canadian Pharmacists Association, December 2010 [7]

Canada and the US are not the only countries affected by drug shortages. Drug supply chains are generally managed on a global level and disruptions can impact global supply [4, 25, 32]

Drug shortages have knock-on effects and impact the whole healthcare system

Santé Canada Health Canada

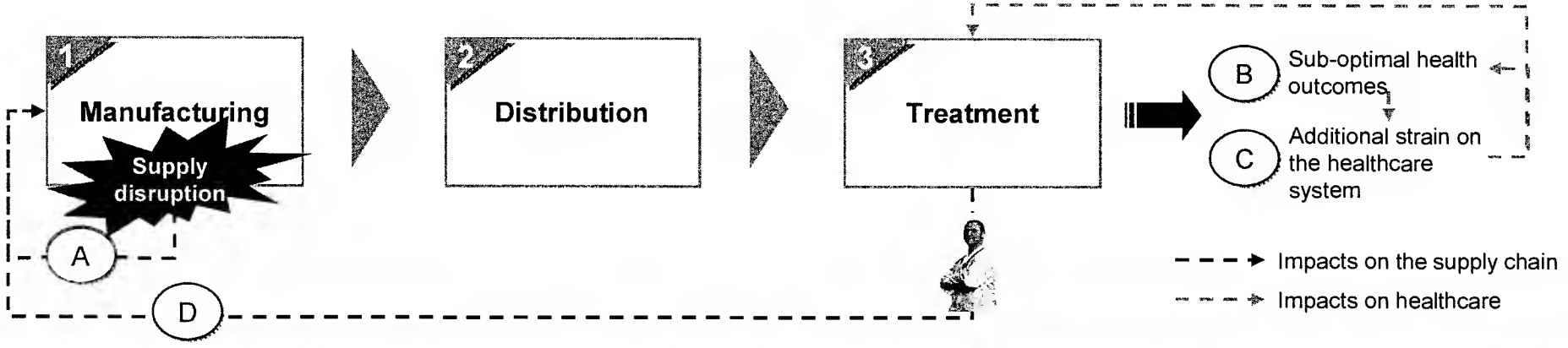
Drug shortages occur almost exclusively at the manufacturing stage creating:

A. A knock-on drug shortage – when one firm fails, the remaining suppliers come under strain[12,14]

B. Anxiety for the patient, especially where the drug has is life-saving or has a significant impact on patient quality of life [3,13]
   - Unscheduled therapy switching negatively impacts health outcomes and places additional strain on the healthcare system [3,13]

C. Additional and unforeseen pressure on healthcare resources (time and expenditure) costing the U.S. an average $216M per year [27]
   - Time consumed in locating residual stock and/or finding suitable therapeutic alternatives [3,5,12,13]
   - Delays in treatment due to lack of suitable alternatives or requirement for education on alternative therapies [3]
   - Therapy switching and/or treatment delays leading to sub-optimal health outcomes (sub-optimal therapies or errors in administration) requiring additional medical attention [3,5,13]
   - Price increases on existing stock from 8-1000 times regular cost [3,5,11]

D. Strain on supply of therapeutic alternatives as physicians switch treatments [12]



Movement towards leaner practices such as "just-in-time" inventory control as well as industry consolidation compound the impacts of drug shortages [4, 25, 32]

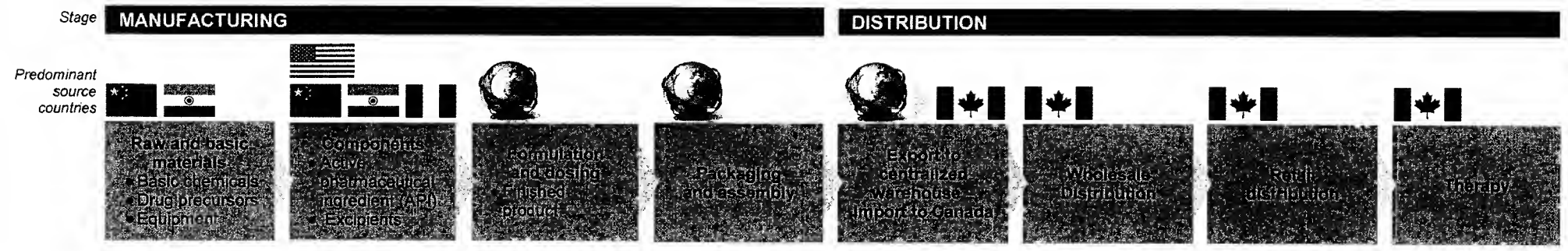
Drug Supply Chains

High-level overview

SECOR

Santé Canada Health Canada

Branded Small-molecule Supply Chain



Example companies	Refined and basic chemical manufacturers Drug Intermediate manufacturers Equipment suppliers	Brand manufacturers for some products (usually single production sites per product) e.g. Abbott, Novartis, etc. API manufacturers e.g. • China Shijiazhuang Pharmaceutical Group • Taj Pharmaceuticals *(India)*	Brand manufacturers undertaking formulation finishing and packaging General Contract manufacturers	Brand manufacturer central warehouse and distribution centre	Canadian brand subsidiary	Wholesalers e.g. • McKesson • Kohl & Frisch • Unipharm Self-distributing pharmacy chains e.g. • Shoppers Drug Mart • Sobeys Pharmacy Group	Hospital pharmacies Retail pharmacies e.g. • London Drugs • Independent pharmacies	Patient

Consolidation of the brand drug manufacturing industry

- Pfizer acquired Wyeth in 2009 [16]
- Merck and Schering-Plough merged in 2009 [17]
- Sanofi-Aventis acquired Genzyme in 2011 [18]

Source: SECOR literature scan, interview with [redacted] Hoffman LaRoche), Interview with [redacted] Oncozyme, [redacted]

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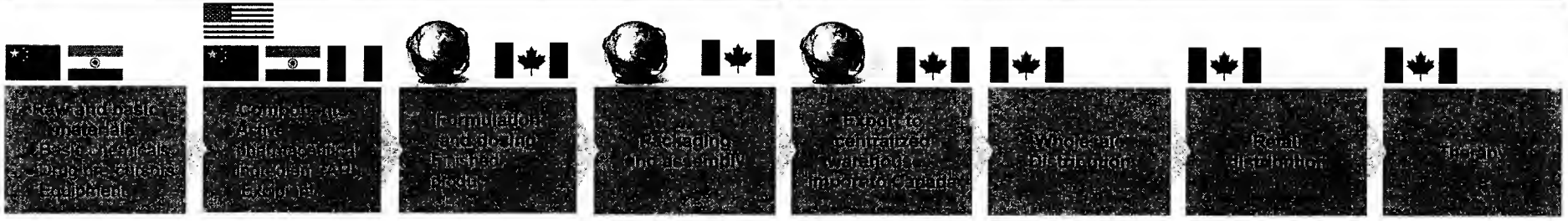
Generic Small-molecule Supply Chain

Santé Canada Health Canada



Example companies	Refined and basic chemical manufacturers Drug Intermediate manufacturers Equipment suppliers	Generic manufacturer (usually one production site per drug) e.g. Apotex *(CAN)*, Sandoz (CAN), Pharmascience (CAN), Teva *(US)* Generic manufacturers (some products; usually one production site per product) e.g. Dr Reddy's (India), Ranbaxy (India) API manufacturers e.g. • China Shijiazhuang Pharmaceutical Group and Tianjin J&K • Taj Pharmaceuticals *(India)* Generic manufacturers *(some products)* e.g. Pharmascience (CAN), Ranbaxy *(India)* General Contract manufacturers	Generic manufacturer central warehouse and distribution centre	Canadian brand subsidiary Canadian generic brand Canadian Wholesalers e.g. • McKesson • Kohl & Frisch • Unipharm Self-distributing pharmacy chains e.g. • Shoppers Drug Mart • Sobeys Pharmacy Group • Familiprix. Hospital pharmacies Retail pharmacies e.g. • Shoppers Drug Mart • London Drugs Patient

Consolidation of the generic drug manufacturing industry

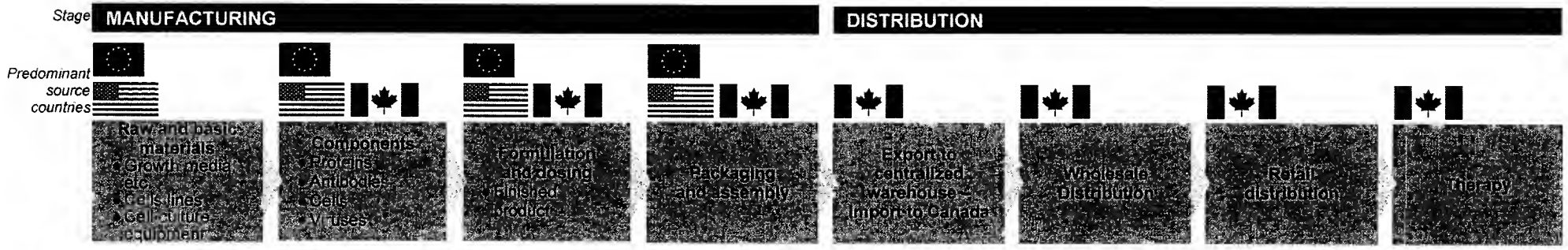
- Teva acquired Ratiopharm in 2010 after acquiring Barr in 2008 [19]
- Watson acquired Cobalt in 2010 [20]
- Mylan acquired Merck's generic division in 2007 [21]
- Hospira acquired Mayne in 2007 [22]

Source: SECOR literature scan, interview with the Canadian Generic Pharmaceutical Association)

s.19(1)

Santé Canada Health Canada

Biologics Supply Chain (excludes vaccines)



Example companies

Cell line and culture suppliers e.g. Millipore SigmaAldrich

Equipment suppliers

Some brand name manufacturers e.g. Pfizer-Wyeth, AstraZeneca, Roche

Commercial collaborations

Biotechnology companies e.g. Amgen, Gilead, Celgene

Certain generic manufacturers for subsequent entry biologics (biosimilars) e.g. Teva

General contract manufacturers (minor)

Brand/ generic manufacturer central warehouse and distribution centre

Canadian brand/ biotech subsidiary

Canadian commercial importer

Canadian Wholesalers e.g.
- McKesson
- Amerisource Bergen

Hospital pharmacies

Retail pharmacies (minor) for select small proteins e.g. insulin

Patient

Source: SECOR literature scan, Interview with [redacted] *Oncozyme*

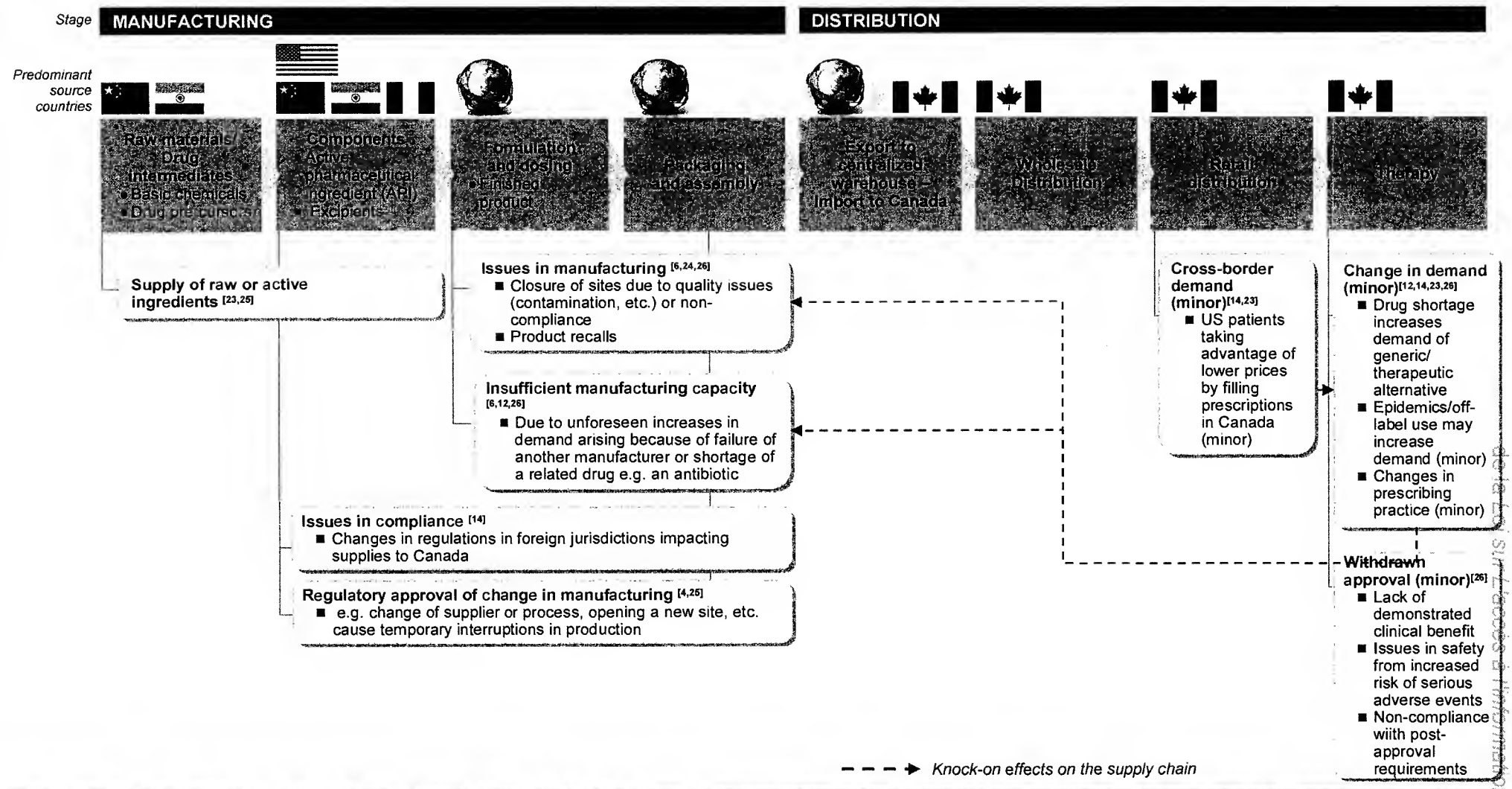
Drug Shortages

Points of failure in supply

SECOR

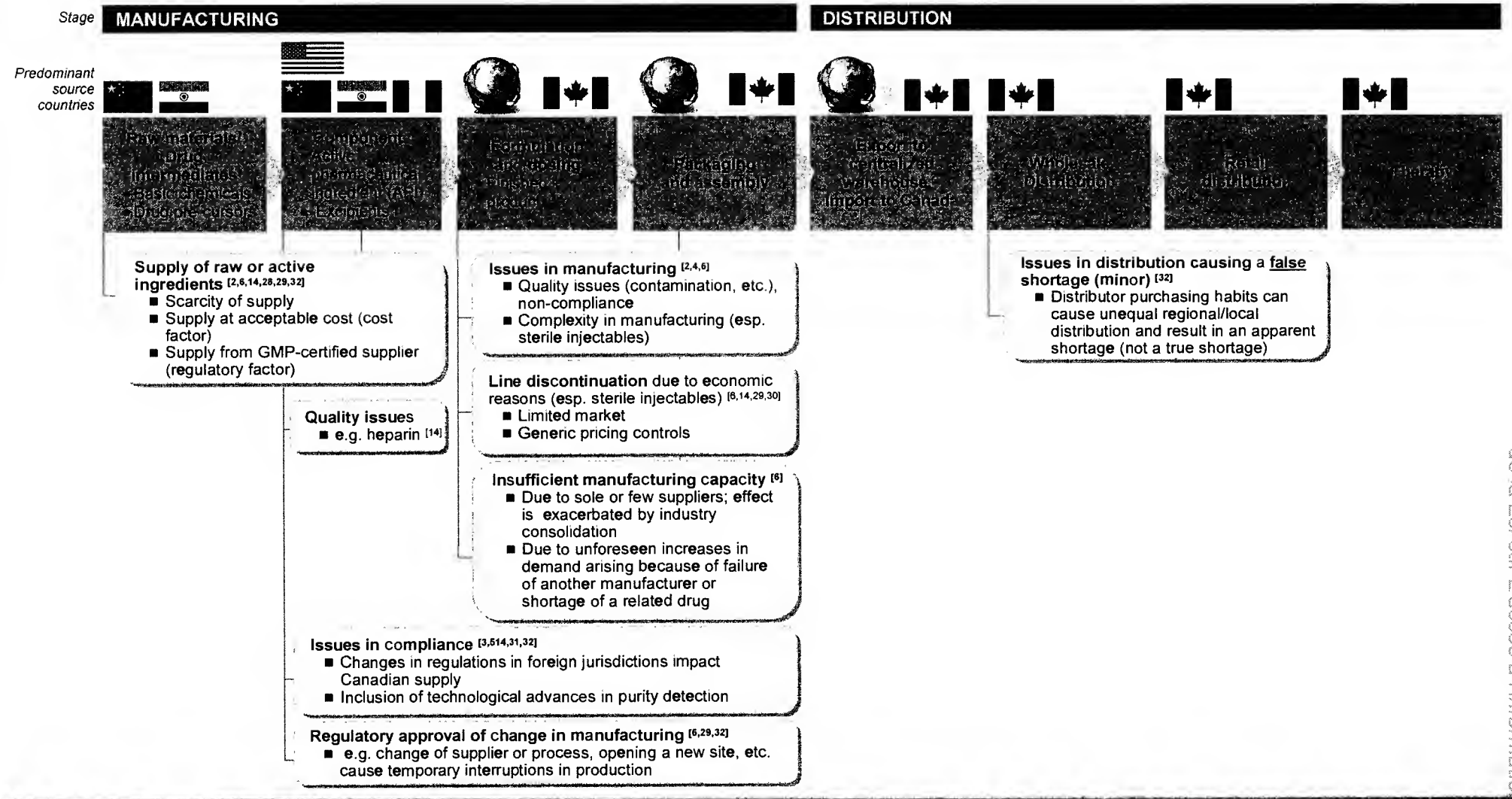
Brand drug shortages occur mostly during formulation and to a minor extent at the therapy stage

Santé Canada Health Canada



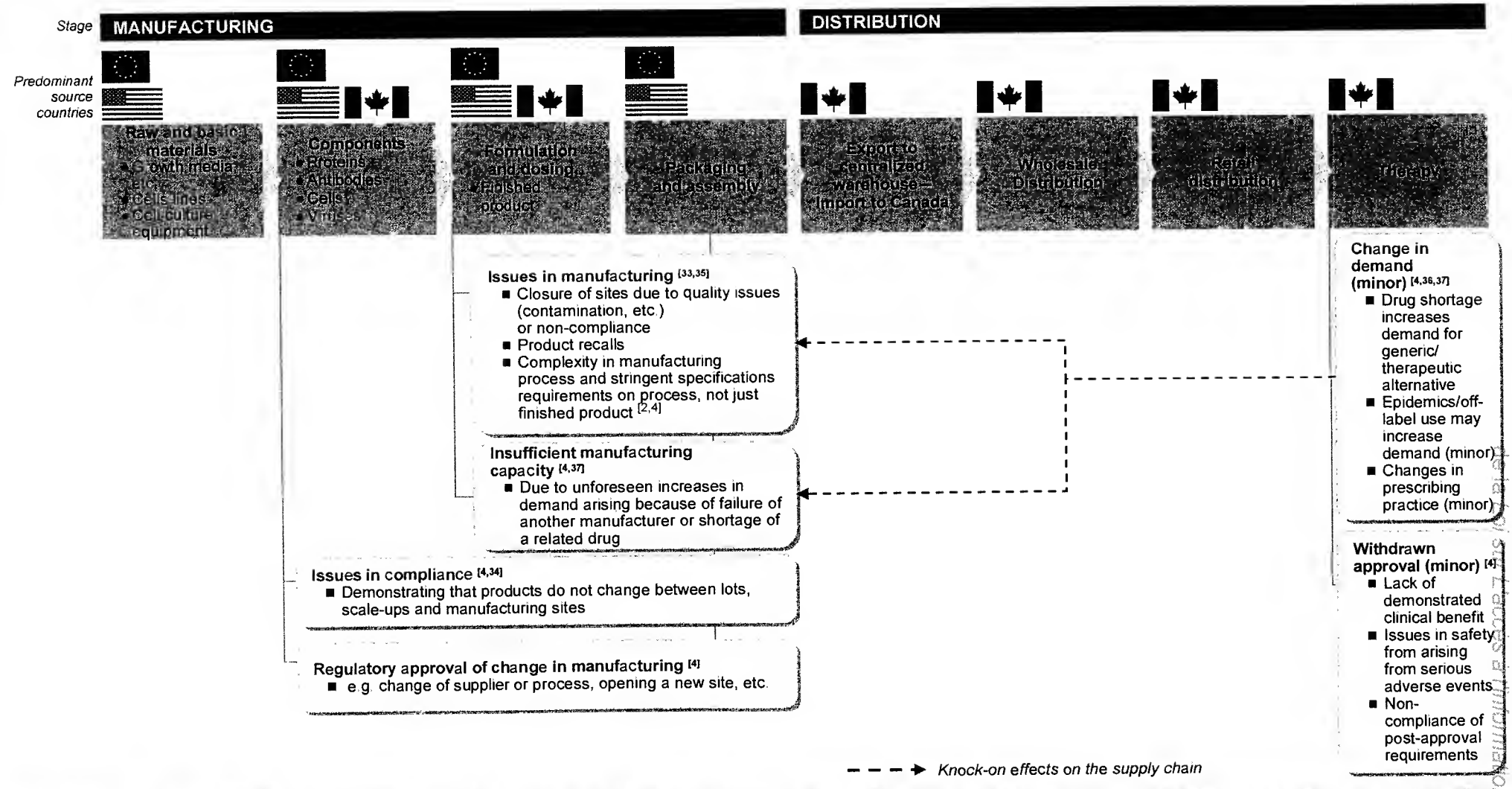
Generic drug shortages typically occur in the ingredient sourcing and the formulation stages

Santé Canada Health Canada



Santé Canada Health Canada

Biologics Supply Chain (excludes vaccines)



Best Practices

SECOR

Canadian stakeholders can mitigate some drug shortages by modifying its current practices

Santé Canada Health Canada

Current challenge	Mitigation strategy	Reference
No early warning of anticipated disruptions due to: ■ Issues in manufacturing ■ Line discontinuations *Currently, drug shortages are typically flagged at the point of therapy i.e. pharmacist*	Create a **notification requirement** from suppliers for sole or limited source products ■ Notification of manufacturing problems could provide 3 months lead time for action given that inventory will still be present in the supply chain[29] ■ Currently, the FDA requires manufacturers who are sole suppliers of a medically-necessary drug to notify the FDA of a discontinuation • The FDA's definition of medically-necessary drug is one used to treat life-supporting, life-sustaining, or debilitating disease. Legislation has been submitted to revise the definition and expand drug notification requirements	3, 38, 44
	Track disruptions and publish information on a dedicated portal ■ Outside of Canada, countries such as the USA and the UK track and publish drug shortages ■ In Canada, the University of Saskatchewan's Drug Information Services provides a similar service to the FDA's drug shortage program	1, 3, 8, 38
Delay in obtaining regulatory approval of change in manufacturing	**Speed up approvals** for drugs where there are few or no other suppliers; applies to: ■ Changes in manufacturing processes/sites ■ New manufacturing sites ■ New API and raw material suppliers	3, 40, 41
Insufficient manufacturing capacity	**Warn other suppliers** of expected shortages/discontinuations so that they have sufficient lead time to meet increased demand	41
Line discontinuation	**Temporary approvals** for import of unapproved drug during shortages (already done by Health Canada)	40, 41, 42
	Provide an **approved list of therapeutic alternatives** and warn suppliers of these may be subject to increased demand ■ Due to the nature of prescription drug reimbursement in Canada, alternative therapies may not be covered by the patient's plan	8
Changes in regulations in foreign jurisdictions impacting Canadian supply	**Monitor foreign regulatory agencies** for changes in regulations so as to anticipate potential impacts on Canadian drug supply	
Scarcity of raw active ingredients	**Locate foreign manufacturers** approved by collaborating regulatory agencies for temporary import of the drug to Canada	41
Delay caused by time required to locate residual supply	Launch a **pharmacy support program** that allows pharmacies within a hospital or retail chain to identify residual stocks of disrupted drug to better manage patient therapy	43

Appendix

SECOR

Santé Canada Health Canada

Bibliography

Topic	Title of Source	Link (where available)
U.S. drug shortages	[1] Drug Shortages Program, FDA	http://www.fda.gov/drugs/drugsafety/drugshortages/default.htm
	[2] Drug Shortages: A Challenge to Patient Safety, presentation by Christina Michalek at the Healthcare Business Summit, Las Vegas April 2011 (original source data: CDER)	http://www.medassets.com/2011-HBS/Performance-Forum/Documents/Handout-Christina-Michalek.pdf
	[3] Drug Shortages Summit Summary Report, November 5, 2010	http://www.ashp.org/drugshortages/summitreport
	[4] Interview with [redacted] Oncozyme, [redacted]	
	[5] Drug Supply Disruptions: Environmental Scan, CADTH, March 2011	http://www.cadth.ca/media/pdf/Drug_Supply_Disruptions_es-18_e.pdf
	[6] SECOR analysis of current drug shortages listed on the FDA's website (website accessed 20 June 2011)	http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm
	[27] Impact of drug shortages on U.S. health systems, American Journal of Health-system Pharmacy, Vol 68, 2011	http://www.ajhp.org/site/DrugShortages.pdf?fm_preview=1
Canadian drug shortages	[7] Canadian Drug Shortages Survey, Canadian Pharmacists Association, December 2010	http://www.pharmacists.ca/content/About_CPHA/Whats_Happening/CPhA_in_the_News/CPhADrugShortagesReport_Dec2010.pdf
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Executive Correspondence Division - Capsule Synopsis of French Correspondence

Docket Number: 11-001494-467

Correspondent: [redacted]

Incoming

[redacted]

Response

I am aware of a number of recent drug shortages and concerned about the significant impact they can have on patients and health professionals, who are forced to consider and identify other therapeutic options. I regret the delay in responding.

Since drugs are manufactured and supplied by the pharmaceutical industry, it is generally accepted that industry is responsible for understanding the supply needs for their product, managing drug supplies, and taking steps to prevent supply interruptions of products that are medically important.

As a regulator, Health Canada is responsible for ensuring that products sold in Canada meet high standards with respect to safety, efficacy and quality. The Department works with manufacturers to minimize the impact of shortages and ensures that information about shortages is made available to those who need it. However, Health Canada cannot require a manufacturer to market a product in Canada or maintain adequate supplies to meet the needs of patients.

In response to the recent reports that shortages are increasing and significantly affecting patient care, I have asked my officials to further explore this issue. The Department has been in contact with industry, pharmacists, physicians, and drug plan managers in several provinces. As well, we have asked the Canadian Agency for Drugs and Technologies in Health to do an environmental scan.

.../2

We are also reviewing international best practices to assess how they collect and disseminate information, and manage drug shortages; and my officials are in contact with industry about their preparedness to disclose critical information about current drug shortages which might have an adverse affect on the health of Canadians.

I appreciate being apprised of your concerns on this issue, and have forwarded your comments to my officials, for their consideration. If you would like to further discuss this issue, please contact Mr. David K. Lee, Director, Office of Legislative and Regulatory Modernization, Health Products and Food Branch, Health Canada, by e-mail at david.k.lee@hc-sc.gc.ca.

s.19(1)

Executive Correspondence Division - Capsule Synopsis of French Correspondence

Docket Number: 11-004344 - 456

Correspondent: [redacted]

Incoming Synopsis:

[redacted]

.../2

Response:

I am aware of a number of recent drug shortages and am concerned about the significant impact these shortages can have on patients and health professionals, who are forced to consider and identify other therapeutic options.

As a regulator, Health Canada is responsible for assessing that products sold on the Canadian market meet high standards with respect to safety, efficacy and quality. However, the Department has no authority to require a manufacturer to bring a product to the Canadian market or to maintain adequate supplies on the market to meet the needs of patients. Manufacturers are the best source for information regarding the supply of a drug. AA Pharma Inc. is currently the only manufacturer of primidone in Canada. For any questions relating to product availability, they should be contacted directly by mail at 1165 Creditstone Road, Unit 1, Vaughan, Ontario L4K 4N7, by telephone at 905-669-0528, or by facsimilie at 905-669-9567.

In March of this year I wrote to a number of industry associations asking that they establish a plan to share information on drug shortages with health professionals. I am encouraged to learn that these association, along with others, have joined together to form a working group and that this group plans to report to me its progress. During these meetings, I have encouraged them to also consider measures through which they can reduce drug shortages.

As these organizations proceed with their work, I have asked that they consider that an effective plan must include an agreed to standard for sustained notifications of drug shortages to health professionals that is timely, accurate, and comprehensive. Should the proposed plan fall short on any one of these elements, Health Canada is prepared to proceed with a regulatory proposal for the mandatory disclosure of shortage information.

In light of the importance of this issue and its impact on patients, I have asked that they submit to me the details of their plan by September 30, 2011. In the interim, I have also asked that they work with Mr. Paul Glover, Assistant Deputy Minister of the Health Products and Food Branch, so that he may participate in and monitor progress of the dialogue on this important issue for Canadians.

I am encouraged by the progress to date. While my preference would be for the number of drug shortages to decline, providing practitioners with timely information will help minimize the effects of these shortages on patients.

To address your specific concerns as it relates to primidone, use of primidone in the treatment of essential tremors is currently not an authorized indication of this drug in Canada. The decision to prescribe a drug for a particular patient is considered the practice of medicine which does not fall under Health Canada's jurisdiction.

In the meantime, there are options for patients affected by drug shortages. Health Canada's Special Access Programme (SAP) provides access to nonmarketed drugs for practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or unavailable.

It is important to note that all requests made to the SAP are practitioner initiated and the regulatory authority supporting the programme is discretionary, where a decision to authorize or deny a request is made on a case-by-case basis. A physician may obtain more information through the SAP website at http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/index-fra.php. They may also contact a programme officer by telephone at 613-941-2108, by facsimile at 613-941-3194, or by e-mail at sapdrugs@hc-sc.gc.ca.

ADVICE TO THE MINISTER

SUBJECT

DRUGS – DRUG SHORTAGES

ANTICIPATED QUESTION

What measures is Health Canada undertaking to address drug shortages in Canada?

- Health Canada is aware of a number of recent drug shortages involving generic and brand name drugs, and recognizes the impact these can have on patients and the people who care for them.

- Causes of drug shortages are complex. Where possible, Health Canada works with manufacturers to minimize the impacts of shortages.

- I have written to industry and practitioners to promote a collaborative approach on this important issue, and am encouraged to learn that discussions to address drug shortages are well underway.

- If a voluntary approach fails to materialize, a regulatory regime obligating manufacturers to disclose information about drug shortages may be necessary.

BACKGROUND:

In October 2010, the Department initiated a series of Technical Discussions to discuss proposals to modernize the regulatory system for therapeutic products. The sessions brought together stakeholders from industry, health professional, academic, patient and consumer groups, and covered a broad range of topics within the regulatory process. A discussion paper on access issues related to drug shortages and discontinuations was presented and discussed. The paper outlined a model to support mandatory notification of drug shortages.

On December 15, 2010, the CPhA released a report on drug shortages. The report claimed that drug shortages were increasing in Canada and highlighted the impact on patients and health professionals. It also provided recommendations for addressing the issue, including the requirement for more timely and accessible notification of shortages. The release of this report coincided with media reports that noted that shortages were primarily occurring with commonly prescribed generic drugs.

On January 6, 2011, the Minister of Health noted that there was a need for improved management of drug shortages in Canada.

Finally, on February 10, 2011, the Canadian Medical Association released results from a poll of its members. The results noted that 74 per cent of 743 respondents had faced difficulty getting prescriptions for generic drugs filled.

Drug Shortages

In most cases, supply interruptions are manageable issues that are dealt with by industry and health professionals. A small portion will result in on-market drug shortages that can lead to treatment interruptions for patients and may also impact health professionals and industry.

Drugs are manufactured and supplied by industry. As such, it is generally accepted that industry is responsible for understanding the supply needs for their product on the market, for managing drug supplies, and for taking steps to prevent supply interruptions.

Role of Health Canada

As a regulator, Health Canada is responsible for ensuring that products sold on the Canadian market meet high standards with respect to safety, efficacy and quality (before they are sold on the Canadian market). Where possible, Health Canada will work with manufacturers, health professionals and patient groups to minimize the impacts of shortages, and to facilitate access to alternatives. However, the Department has no authority to require a manufacturer to supply products to the Canadian market or to maintain adequate supplies to meet patient demand.

Current Status

In light of the recent challenges caused by drug shortages, the Department initiated policy work to develop a better understanding of the impact and explore the Department's role in monitoring or responding to drug shortages in our capacity as a regulator.

At the beginning of January 2011, Health Canada requested that the Canadian Agency for Drugs and Technology in Health (CADTH) undertake an environmental scan of drug shortages. The final report was recently posted - it describes various factors that can impact the drug supply chain and acknowledges that no organization is responsible for the provision of information regarding drug shortages in Canada and, consequently, there is very little information on supply interruptions. As a result, the report is unable to definitively establish the prevalence or cause(s) of drug shortages.

In March of 2011, the Minister requested that industry associations work with practitioners to voluntarily disclose information on drug shortages. On April 18, 2011, industry and practitioner associations met to discuss how drug shortage information could be shared. This group has indicated a willingness to report to the Minister on its progress.

In June of 2011, the Deputy Minister raised this issue with provincial and territorial deputy ministers at the Conference of Deputy Ministers of Health (CDM). The deputies acknowledged that drug shortages are an important issue and asked that Health Canada report back on progress made with industry and practitioner groups.

CONTACT INFORMATION

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Approved by:	Telephone:

FOR INFORMATION

10-076781-858

BRIEFING NOTE TO THE ACTING ASSOCIATEDEPUTY MINISTER

Drug Safety and Effectiveness Steering Committee Teleconference
10 June 2011, 12:30 to 1:30 (EST)

ISSUE:

The Acing Associate DM will be asked to approve the two step proposal to develop and formalized the two stage process

BACKGROUND:

Organization: The CPhA is a national association advocating for pharmacists in Canada; pharmacist membership in the association is voluntary. The CPhA promotes the importance of the pharmacists' contribution to Canadian health care as the drug expert and partner in provision of high-quality drug therapy.

Report: The CPhA conducted an online poll of 427 pharmacists (approximately 33,000 pharmacists in Canada). In 2004, it produced a similar report, polling approximately 200 pharmacists. In the 2010 report, 34% of the 427 respondents were from Quebec, and 86% of this group were hospital pharmacists. Only 20% of the total respondents were from Ontario. In the 2010 report, 30% of the total respondents were hospital pharmacists, whereas those in 2004 were exclusively community pharmacists. Hospital and community pharmacists dispense different drugs and employ different forms of administration. These factors and the different survey methodologies used limit the utility of comparing the data in the two studies.

CURRENT STATUS:

In the 2004 study, 80.2% of respondents indicated having difficulty locating prescriptions over the previous week. The 2010 report indicates 93.7% of pharmacists had difficulty locating prescriptions, an increase of approximately 10% over six years. In 2010, pharmacists estimated that they had difficulty locating approximately 10 prescriptions per week, an increase from 4.2 prescriptions in 2004.

The study fails to note whether this increase was impacted by growth in the total number of drugs dispensed per day. In the 2010 study, 62% of respondents indicated that notification of shortages (from wholesalers, manufacturers, etc.) was limited. In the 2004 study, 70% did not receive notification. In 2010, more than half the respondents claimed shortages had inconvenienced patients and adversely impacted patients health outcomes, this question was not included in the 2004 survey.

CONSIDERATIONS:

While the number of pharmacists who indicate experiencing shortages appears to have increased, data limitations and survey methodology undermine the CPhA's recent findings. Provincial pharmacists' associations in Saskatchewan and Quebec have made similar claims regarding drug shortages but their evidence is limited or anecdotal. There have also been reports of shortages of certain classes of drugs (anaesthetics, oncology, etc.) in the United States.

Potential Causes of Shortages
Despite the existence of complex mechanisms at various points in the drug supply chain to anticipate and respond to drug shortages, drug supply problems are not uncommon. There are a number of possible causes: shortages of raw materials, production problems, business decisions, delays due to regulatory requirements, production disincentives due to pricing regimes, product recalls, and production monopolies. Each factor, in isolation or in combination with other factors, may contribute to a specific shortage.

The reasons for supply disruptions are often known exclusively to drug manufacturers, and this information is largely proprietary. Production is increasingly outsourced internationally and the market authorization holder may not be aware of delays from suppliers. Most supply issues are handled appropriately at various points along the drug supply chain.

CONCLUSION:

The CPhA report has presented one perspective on possible challenges on this topic. Health Canada will continue to monitor the situation, but the responsibility for the day-to-day management of the pharmaceutical supply chain remains in the business domain.

Deputy Minister's Office

MECS# 10-076781-858

Branch Head: Abby Hoffman, Associate ADM, SPB
Telephone: 946-1791

Attachments(s)

Appendix A - Canadian Drug Shortages Survey (2010)
Appendix B - Administrative Burden on Canadian Pharmacists of Drug Shortages (2004)

Drug Supply Disruptions

March 2011

Environmental Scan

Context

While drug shortages are not uncommon,[1,2] their frequency and duration may be escalating.[3] Drug shortages are currently believed to be more prevalent in the generic drug market in Canada, than in the brand name market.[4]

Unanticipated and poorly communicated drug shortages and discontinuations in drug product lines may impact the delivery of patient care.[2,3] The effect on the delivery of health care services, particularly with regard to the administrative resources required to source alternative drug therapies and the financial consequences of substitute therapies (which are often more expensive) are other areas of impact of drug shortages.[2,3]

The problems encountered by disruptions in drug supplies are often magnified by the absence of advanced warning from drug manufacturers. This is of particular concern when the affected drugs are sourced from single or primary suppliers.

Many factors can influence the occurrence and severity of drug shortages.[5] The most frequently cited reasons for shortages in the drug supply chain include issues relating to raw and bulk material suppliers, manufacturers, wholesalers, distributors, and regulatory bodies.[3]

Concern that drug shortages may continue during the coming years[6] underscores the need for strategies and procedures, at every level of the drug supply chain, to minimize disruptions to patient care.

Objectives

The purpose of this report is to provide information on the causes and impact of drug shortages in Canada. The following questions will be addressed:

- What, if any, drugs have been in short supply in Canada?
- If drugs are in short supply, are they generic or brand name, and are they single or multi-source products?
- What are the main causes and the impact of drug shortages?
- What is the international drug shortage experience?
- What strategies can be implemented at various levels of the health care system to mitigate drug shortages?

Findings

The findings of this environmental scan are not intended to provide a comprehensive review of the topic. Results are based on a limited literature search and communication with key informants. This report is based on information gathered as of February 14, 2011.

The first section of this report will present information on general drug shortage issues in Canada and will include a list of drugs that have been identified as being in short supply. The second section will explore the international drug shortage issue with a specific focus on the United States (US), Europe, Australia, and New Zealand. The third section of this report will review the causes and impact of drug shortages, and the final section will identify strategies, guidelines, and recommendations that can be implemented to minimize the impact of drug shortages.

For the purpose of this report a drug shortage is defined as "any time when commonly stocked drugs are either not available to fill a prescription in a pharmacy, or when distributors or manufacturers are unable to supply a drug."[7]

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Drug Shortages in Canada

It is difficult to quantify and determine the extent of drug shortages in Canada because manufacturers are not required to report disruptions in drug supply to Health Canada and because there is no single accountable Canadian organization that provides system-wide drug distribution oversight.[3] Nonetheless, Canadian health practitioner associations[3,6] and the media[4,8-10] provide reports of drug shortages.

In December 2010, the Canadian Pharmacists Association (CPhA) published the results of a national survey on drug shortages.[3] The survey results are based on the opinions of more than 427 pharmacists (representing approximately 1.4 per cent of all Canadian pharmacists[11]). The report asserts that drug shortages are having a "detrimental impact on the health of Canadians and the ability of pharmacists to care for patients." Manufacturers' reluctance to share information is recognized as a significant barrier to increasing the awareness of drug shortages. The report points to the US Center for Drug Evaluation and Research's Drug Shortage Program as a potential model from which Canada can learn. The 2010 report compared the drug shortages with a similar 2004 CPhA report[7] and noted that current drug shortages are "more widespread and prolonged."

In March 2010, the Saskatchewan College of Pharmacists conducted a provincial survey[6] of 159 community pharmacy managers on the disruption in supply and/or shortages of prescription drugs. The survey identified 15 drugs that accounted for 75 per cent of the reported shortages. Ninety-one per cent of survey respondents reported that shortages were due to manufacturing problems and that no advance warning was issued by manufacturers on impending shortages.

The Canadian Anesthesiologists' Society is currently investigating disruptions in the supply of propofol to determine whether its supply status meets the definition of a drug shortage.[12] The society is also concerned about the discontinuation of sodium thiopental.[10] Although there are therapeutic alternatives to sodium thiopental, it is the anesthetic commonly used for geriatric, cardiovascular, and obstetric patients.[10] Shortages of these two drugs could lead to the cancellation of surgeries and other medical procedures.

The Canadian Society of Hospital Pharmacists has expressed concern about drug shortages, particularly for drugs that do not have therapeutic alternatives.[8] The Canadian Medical Association has suggested that a national drug strategy is needed to oversee drug shortage issues and to prepare for shortages.[4]

In an effort to determine which drugs are currently in shortage in Canada, CADTH conducted a survey of jurisdictional drug plan managers. The reported shortages were for penicillin, amitriptyline, pentoxifylline, and propofol; with five jurisdictions reporting shortages of these drugs. Four jurisdictions reported shortages of cephalexin. Numerous jurisdictional shortages were reported for diltiazem, verapamil, allopurinol, clonidine, triazolam, pentothal, and carbidopa-levodopa.

The drugs listed in Table 1 as being in short supply are based on anecdotal sources drawn from the CPhA's 2010 survey,[3] CADTH's jurisdictional survey of drug plan managers, and sources captured in the media during the period from October 2010 to February 2011. It is acknowledged that this is not a comprehensive list and that disruptions in the supply of some of these drugs may have been resolved since reporting. It should also be noted that none of the drugs listed in Table 1 has been verified with manufacturers as being in shortage.

Of the 55 drugs reported in shortage, 46 were from the generic pharmaceutical industry. Of these, 10 were from a single-source supplier erythromycin, flunisolide, maprotiline, methotrimeprazine, mitomycin, propofol, triazolam, and Nine brand name drugs were listed, all from single-source suppliers (benztropine mesylate, danaparoid sodium, dexrazoxane, fosphenytoin sodium, interferon alfa-2B, procainamide, thyrotropin, and hepatitis A and B vaccine).

Table 1: Reported Drug Shortages in Canada from October 2010 to February 2011*		
Non-Proprietary Drug Name	**Brand / Generic**	**Single- / Multi-Source**
Allopurinol	G	M
Amitriptyline	G	M
Amoxicillin-Clavulanic acid	G	M
Betahistine	G	M
	G	M
Benztropine mesylate	B	S
	G	M
Carbidopa-levodopa	G	M
Cefprozil	G	M
Cephalexin	G	M
	B	S
Clonidine	G	M
Danaparoid sodium	B	S
	G	S
Dexrazoxane	B	S
Digoxin	G	M
Diltiazem	G	M
Doxycycline	G	M
Erythromycin	G	S
	G	S
Fluconazole	G	M
Flunisolide	G	S
Folic acid	G	M
Fosphenytoin sodium	B	S
	G	M
Glimepiride	G	M
Heparin	G	M
Hepatitis A and B vaccine	B	S
Interferon alfa-2B	B	S
	G	M
Lisinopril-Hydrochlorothiazide	G	M
Maprotiline	G	S
Mefenamic acid	G	M
Methotrimeprazine	G	S
Metoclopramide	G	M
	G	M
Mitomycin	G	S
	G	M
Nortriptyline	G	M
Penicillin	G	M
Pentoxifylline	G	M
Phenobarbital	G	M
Piroxicam	G	M
Prazosin	G	M
Procainamide	B	S

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Table 1: Reported Drug Shortages in Canada from October 2010 to February 2011*

Non-Proprietary Drug Name	Brand / Generic	Single- / Multi-Source
Prochlorperazine	G	M
Propofol	G	S
[redacted]	G	M
Salbutamol (inhaler)	G	M
Sodium pentothal	G	S
Thyrotropin alfa	B	S
Triazolam	G	S
[redacted]	G	S
Valcyclovir	G	M
Verapamil	G	M

B = brand name manufacturer; G = generic manufacturer; M = multi-source product; S = single-source product,.
*Limitations of this table: based on information from the CPhA survey, drug plan managers, and media stories. Drugs on this list have not been confirmed by manufacturers as being in short supply.

International Drug Shortages

United States

Globalization of the pharmaceutical industry has made supply disruptions for some drug products an international concern.[3] Drug shortages encountered in the US may be a good indicator of shortages in Canada, as the drug inventories between the two countries are integrated.[13]

Recent drug shortages in the US have been described as "life threatening"[14] and are believed to be the worst in 20 years.[15] As of February 6, 2011, approximately 52 drugs have been reported on the Food and Drug Administration's (FDA's) Current Drug Shortages list.[16] The reasons reported for the shortages were manufacturer delays in 30 cases and increased demand in 11 cases. As of February 9, 2011, the American Society of Health System Pharmacists (ASHP) lists more than 150 drugs as being in short supply.[17] The discrepancies between the FDA and ASHP lists are likely due to the fact that the FDA list is reliant on self-reported drug shortages from manufacturers, while the ASHP receives input from its members and others responsible for managing drug product inventories. These lists are ever changing as shortages are resolved and new drugs in shortage are added.

The Drug Shortage Program, within the Center for Drug Evaluation and Research, addresses "potential or actual shortages of prescription, over-the-counter, or generic drugs that have a significant impact on public health."[16] The Drug Shortage Program works with drug manufacturers, review divisions, compliance and other departments of the FDA to manage product shortages.

The FDA has limited authority to resolve drug shortage issues because drug manufacturers are obliged to report only discontinuations of single-source, medically necessary drugs. New legislation is designed to change this. The *Preserving Access to Life-Saving Medications Act*, introduced into the Senate in February 2011, would require drug manufacturers to give early notification to the FDA on incidents that could cause a drug shortage. The legislation would direct the FDA to provide up-to-date public notification of drug shortages and actions taken to address them. The legislation would also give the FDA the authority to require early notification from drug manufacturers when they decide to limit or discontinue drugs.[18]

From July 2010 to September 2010, the Institute for Safe Medication Practices (ISMP) polled more than 1,800 US health care practitioners to determine their experiences with disruptions in drug supplies. Respondents reported that the increase in volume of "critically important" drug shortages was a major concern. The survey revealed that two patient deaths had been attributed to dosing errors from the use of an unfamiliar alternative to morphine.[14] It was noted that substitute drugs are often difficult to find and the sudden demand for them can lead to a shortage in their supply.[9] In addition, the lack of advanced warning about an impending

shortage and the number of health care practitioner hours lost to searching for therapeutic alternatives were major concerns.[19]

In November 2010, a Drug Shortage Summit was jointly held by the American Society of Anesthesiologists, the American Society of Clinical Oncology, the ASHP, and the ISMP. Initial recommendations for managing shortages were developed during the summit. Participants commented on the need for improved communication between stakeholders in the drug supply chain and health care providers.[20]

In the US, sterile injectable products have been particularly susceptible to shortages. According to data collected in 2008 by the FDA's Drug Shortage Program, 35 per cent of all drug shortages involved sterile injectable products. In 2009, this increased to 46 per cent. This growth is believed to be partly a result of the consolidation of industry involved in making generic sterile injectable products, which is now limited to one or two companies.[21]

Until 2009, there were three manufacturers of propofol: Teva Pharmaceuticals, Hospira, and APP Pharmaceuticals. In early October 2009, Hospira recalled their product because of "particulate matter in the vials." This was followed in late October 2009 by a Teva recall of the same drug due to possible microbial contamination. This left one company to supply propofol to the entire US market.[8,22]

As of May 2010, Hospira had not yet returned propofol to the market; however, an update in January 2011 reported intermittent backorders but continued improvements in supply. Teva announced in May 2010 that it would no longer manufacture the drug, citing a difficult manufacturing process with little or no profit.[22]

The FDA dealt with this shortage by exercising its regulatory enforcement discretion by temporarily allowing the importation of an unapproved drug, Fresenius Propoven 1%, a propofol product approved in other countries. The FDA inspected the manufacturing facilities and evaluated the quality of the product to assure safety before allowing this temporary importation.[22]

The causes of sterile injectable product shortages in the US during the period of January 2010 to October 2010 are captured in Table 2.[20]

Europe

Drug shortages in the United Kingdom (UK) have been linked to its weakened currency.[23] In particular, pharmacists have been selling drugs intended for patients in the UK to European markets where profits are more lucrative.[23,24] In an effort to prevent pharmacists from hoarding, repackaging, and selling UK supplies to European countries, a practice known as "parallel trading," manufacturers and wholesalers have imposed quotas on the volume of drugs that UK pharmacies can purchase. While this is difficult to monitor, individual pharmacies are being watched for unusually large orders, which might be an indicator of illegitimate trading. Several years ago, European countries were parallel trading with Britain, but with the weakening of the British currency, the situation has reversed.[25]

Table 2: Causes of Sterile Injectable Shortages in the US: January 2010 to October 2010[20]

Percentage Related to Reason for Shortage	Reason
42%	Product quality issues (includes particulate, microbial contamination, impurities, stability changes)
18%	Discontinuations
18%	Delays / capacity issues
9%	Raw material issues
5%	Closure of manufacturing facilities
4%	Component problems / shortages
4%	Increase in demand due to another drug shortage

In an effort to keep track of drug shortages, the UK's Pharmaceutical Services Negotiating Committee (PSNC) keeps an inventory of drugs in shortage similar to the FDA's Current Drug Shortages list.[16] Along with maintaining the drug shortage list, the PSNC has created contingency plans with manufacturers for dealing with sourcing drugs in shortage.[24]

The UK's Department of Health has issued guidelines to address supply and distribution problems.[26] As well, in December 2010, the Department of Health produced a guideline to inform manufacturers, wholesalers, NHS Trusts, registered pharmacies, and dispensing doctors, of their key legal and ethical obligations in relation to the supply and trading of drugs.[27]

Very little has been reported on drug shortages in Europe, with the exception of the UK. According to the European Medicines Agency (EMA), two drugs are in short supply: agalsidase beta and imiglucerase, both of which are manufactured by Genzyme in the US.[28] To help manage this shortage, the EMA's Committee for Medicinal Products for Human Use issued temporary health care practitioners recommendations regarding patient prioritization for these drugs.[29]

According to the European Commission directive 2001/83/EC, Article 23a, market authorization holders for products marketed in Europe Union member states are required to give two-months notification to regulatory authorities when market access to a product will be temporarily or permanently interrupted.[30]

Australia

While drug shortages have been noted in Australia, they do not appear to be extensive. According to the Therapeutic Goods Administration (TGA) Advisories Group, there is currently a shortage of heparin,[31] methadone,[32] and an anticipated shortage of indomethacin.

In response to the heparin shortage, Australia's Office of Health Protection issued a guideline to clinicians to inform them of alternative anticoagulants.[31]

Methadone tablets have been recalled in Australia because of manufacturing quality control issues. Carbidopa-levodopa, manufactured by Merck Sharp & Dohme (Australia), went into shortage in December 2009. The manufacturer issued a notification that the issue would not be resolved until 2011, depending on regulatory approval.[33]

It is noteworthy that the TGA and the FDA have a cooperative arrangement regarding the exchange of information on current good manufacturing practices that may affect drug shortages in either country.[34]

New Zealand

The Pharmaceutical Management Agency of New Zealand (PHARMAC), a stand-alone crown entity accountable to the Minister of Health, works on behalf of New Zealand's District Health Boards to manage the funding of community drugs.[35] Through its website, New Zealand's drug regulatory body Medsafe refers the public to PHARMAC regarding drug shortage issues.

PHARMAC is involved directly with the drug supply chain. Manufacturers are contractually obliged to notify PHARMAC if inventories fall below a two-month supply and if they become aware of potential shortages.[36] As well, manufacturers are liable for any additional costs accrued in sourcing alternative products, including the cost of replacement drugs.[37] In the past, drug shortages have been blamed on the procurement process and PHARMAC's involvement;[38] however, no recent news stories could be found regarding this issue.

Causes and Impact of Drug Shortages

The drug supply chain is the means through which prescription drugs are delivered to patients. It includes raw materials suppliers, drug manufacturers, wholesale distributors, group purchasing organizations, pharmacies, and drug regulators. Many factors can influence a drug shortage and often there are multiple causes that can affect the shortage of a single drug product. The drug supply system is complex and includes multiple organizations that play varied and occasionally overlapping roles in drug distribution and contracting.[39]

Raw and Bulk Material Issues

The unavailability of raw or bulk materials used to make drugs contributes to drug shortages[20] and is believed to be particularly problematic when an active ingredient is obtained from a single raw material supplier.[40,41]

There are a number of causes of raw material supply disruptions. These may include:

- contamination of raw materials by disease or pollution[41]
- harm to raw materials caused by climatic or other environmental changes[42]
- complicated processing practices (e.g., the extraction process from a natural source such as tree bark)[43]
- damage caused during the harvest, storage, or transportation of raw materials.[41]

The sourcing of raw materials outside of the US is believed to be a major weakness in the drug supply chain.[44] Notably, one of the greatest threats to the supply chain anticipated during the next five years is thought to be contaminated raw materials and nonconformity to established standards.[44]

The inability of raw material processing facilities to consistently observe good manufacturing practice can result in regulatory authorities closing them down.[20] This is more commonplace in countries where regulatory and safety standards are not well observed. Approximately 80 per cent of the active ingredients used in US and European drugs are currently manufactured in China and India,[45] countries that are believed to have less stringently enforced safety and regulatory standards than western regulatory bodies.[46]

As well, there is an increasing trend in China for drug raw material manufacturers to register themselves as chemical companies, a practice that gives them immunity to the scrutiny of Chinese drug regulatory authorities.[47] The heparin incident of 2008 is an example of how a Chinese raw material manufacturer was able to produce active ingredients for heparin even though it did not have the necessary certification to do so. A contaminated batch of heparin was sold to Baxter International, but the source of the contamination originated from the Chinese raw material supplier. The contaminated heparin was responsible for approximately 20 deaths and more than 350 adverse reactions in patients in the US.[48]

Manufacturing Issues

There are numerous manufacturing issues that can create and/or contribute to drug shortages. Single-source drug products are the most vulnerable to shortages, although multi-source products are also susceptible. The latter is particularly the case if the primary manufacturer is affected, since less dominate market participants may not have the resources to supplement the shortfall.[43]

Drug shortages are often difficult to predict because manufacturers are reluctant to share details of shortages. This reluctance is largely due to a fear of losing competitive advantage[6] or due to public relation, legal, and other considerations.[49] It is believed that this lack of transparency can actually intensify drug shortages because contingency plans and strategies cannot be effectively implemented to manage them.[3,42,50] Manufacturers may also be concerned that if they announce a shortage, wholesale distributors and pharmacists may hoard supplies of a drug, a practice that can intensify the impact of a drug shortage.

Identified causes of manufacturing disruptions affecting drug supply include:

- Unanticipated surges in demand for particular products[16] due to the approval of a new indication, usage changes as a result of a new evidence-based practice or new clinical guidelines, or a sudden outbreak of disease.[50]
- Changes in production formulations.[16]
- Changes or problems in the production process, which may include regulatory good manufacturing process enforcement actions.[42]
- Limited manufacturing capacity – often multiple products are produced on the same equipment, which means that an increase in the production of one product will usually result in a production delay of another.[43,51]
- Temporary or permanent discontinuations of products as manufacturers shift production or reallocate resources.[3]

- Voluntary recalls initiated by manufacturers because of potential problems with a drug or manufacturers raising their own quality standards requiring time to comply with them[20](voluntary recalls are usually short-term situations).
- Complex manufacturing processes, such as those used to make sterile injectable products.[51]
- Antiquated manufacturing equipment.[42]
- A business decision to cease production because of lack of financial return, poor demand, or potential safety concerns.[52]
- Industry increasingly manufacturing for a global market – where production decisions for products and market places have become increasingly complex.[53]

There are numerous business decisions that can impact drug shortages. The global economic downturn, patent expirations, and a dearth of pipeline innovations have driven manufacturers to seek internal efficiencies.[54] Many of these efficiencies have been found in the form of job cuts. In 2009, 23,000 jobs were lost to restructuring in the US pharmaceutical industry.[55]

Industry mergers are another means of creating internal efficiencies. In 2009, more than 27,700 jobs were lost in the US pharmaceutical industry as a result of mergers.[55] When companies merge, less profitable product lines are often reduced or discontinued[51] and sometimes manufacturing facilities close.[42] Mergers of companies with similar product lines will see product consolidation, possibly resulting in changing a multi-source product into a single-source product. These consolidation practices result in fewer companies manufacturing drugs, leaving markets vulnerable to shortfalls.

The pharmaceutical industry is currently facing the loss of a large number of patent protections. Drugs worth US$15.3 billion will face generic competition this year,[54] and in 2012, US$33.2 billion will be lost due to patent expirations.[54] This loss in revenue may result in more industry mergers, restructurings, and discontinuations of drugs.

It is believed that there was a time when global drug manufacturers protected certain service products in the interest of patient care: "small and commercially less interesting niche products that were made available as part of a wide product range."[56] It appears that this philosophy has changed and, products such as sodium pentothal, a single-source anesthetic that has a small profit margin, are now discontinued.

Wholesale and Distribution Issues

Wholesale and distribution issues can play a role in drug shortages. Many of these issues relate to inventory management practices. For example, some manufacturers and wholesale distributors may minimize end-of-quarter or end-of-year product inventories as an inventory management strategy. Manufacturers and wholesalers may also limit the shipments of products based on yearly quotas, a practice that can result in product shortages at the pharmacy level.[42]

In addition, many manufacturers, wholesalers, and pharmacies use "just-in-time" inventory control practices that involve keeping minimal supplies of drugs in stock. While this is an attractive cost-saving strategy,[7] it is a practice that can contribute to drug shortages due to an overall reduction of readily available drug inventories.[20]

In order to maintain profit margins, wholesalers may stockpile lower-priced inventory in anticipation of upcoming manufacturer price increases. Similarly, rumoured price increases could lead to stockpiling at the pharmacy level.[42] Stockpiling can also occur because wholesalers and pharmacies believe that a supply shortage is forthcoming, such practices can actually prolong a disruption because they create an artificial shortage.[7]

Delays in the distribution chain from drug manufacturers to wholesalers, and from wholesalers to health system pharmacies could also contribute to drug shortages. These delays could be due to factors such as lengthy contract negotiations or delivery delays.[42]

Price differences between jurisdictional drug formularies, where the price for the same product differs from jurisdiction to jurisdiction, may result in wholesalers selling drugs

preferentially to provinces where profits are more lucrative. This practice may account for the regional differences in drug availability. Contractual agreements with wholesalers and group purchasing organizations may also account for regional variations in drug availability.[20]

It is noteworthy that in Canada and the US, when drug manufacturers sell products to self-distributing pharmacy chains and wholesalers, they relinquish title rights to the product. Manufacturers have no power to redistribute products between buyers once the title transfer has taken place. Thus, shortages that may occur after products have been sold by the manufacturers are not only beyond their control, but are also beyond their knowledge.

Provincial Reimbursement Policies

Generic drugs account for more than 50 per cent of all Canadian prescription drugs, and with more brand name drugs coming off patent, this number is expected to rise.[57] Shortages of generic drugs are increasing in frequency in Canada[58] and there is concern that recent reforms to control generic drug costs may have contributed to the problem. In 2010, provincial drug plans in Ontario, Quebec, and other provinces capped the price of generic drugs at 25 per cent of brand name equivalents pricing, down from 50 per cent.[59]

The substantial cut in profit margins associated with price capping reforms may discourage global drug manufacturers from continuing the production of drugs with profit margins that are already under performing. The Canadian Generic Pharmaceutical Association denies that current generic drug shortages are a response to provincial price capping reforms,[60] stating that shortages predate the legislation that was passed in July 2010. A statement released by the group cited raw material shortages, changes to regulatory standards and requirements, production issues, and changes in production equipment and processes as the contributing factors to generic and brand name drug shortages.[60]

Regulatory Issues

Strict enforcement of good manufacturing practices and other related regulations by drug regulatory bodies may play a role in drug shortages.[61] Various Apotex drug shortages occurred after the Health Canada and FDA regulatory inspections that resulted in the voluntary recall of several products.[61]

In response to the heparin contamination issue in 2008, the FDA increased the number of manufacturer inspections it performs in China and India. [62] In 2009, the FDA had two medical product investigators in China, a country that has more than 900 drug manufacturing facilities,[63] to ensure compliance with current good manufacturing practices. The FDA also has two inspectors in India, where there are approximately 502 drug manufacturing sites.[63] As the FDA increases its resources to manage these inspections, it is possible that the closure of plants that are not in compliance with regulatory standards may contribute to drug shortages.

A joint initiative between the FDA, TGA, and EMA in 2008, set-up partly in response to the heparin contamination issue, may also have an impact on drug shortages. The purpose of the collaboration is to create a joint inspection program for international active pharmaceutical ingredient manufacturers to improve transparency and efficiency in inspection practices and reduce duplication of inspections.[64]

The 2010 Drug Shortages Summit in the US concluded that FDA regulatory barriers and ambiguities, including the lack of regulatory power to require manufacturer drug shortage notification and other actions, were considered to be significant contributors to drug shortages.[20] Health Canada does not require manufacturers to notify them of expected product withdrawals. Similarly, no statutory authority is in place in Canada that can enforce manufacturers to report notifications on the disruptions in the supply of medically necessary drugs. The new legislation, recently introduced into the US Senate, the *Preserving Access to Life-Saving Medications Act*, will help address this issue for the FDA.[18]

New regulatory requirements from Health Canada are also believed to have contributed to drug shortages; in particular, the new policy for Notifiable Changes. Under the old Notifiable Changes policy, if a manufacturer did not receive a written objection from Health Canada

within 90 days, the manufacturer was able to proceed with the change. In September 2009, Health Canada implemented a policy change that would help them to more effectively manage risks associated with changes to drugs. The new reform eliminated the 90-day default clause and now requires drug manufacturers to wait for Health Canada's review and approval before implementing changes.

It is not uncommon for manufacturers to make such changes to drugs. In 2009, 1,073 submissions were received by Health Canada by drug manufacturers for notifiable changes.[65] These are submissions manufacturers must make to Health Canada for changes to previously approved drugs. Many of these changes are made to "improve the quality of the drug product or the efficiency of the manufacturing process, or they could be made for marketing considerations. Changes to the labeling of a drug product could include adding new indications, improving the management of risk for a product by adding warnings, limiting the target population or changes to dosage regime etc..."[66]

Although Health Canada's intention is still to review changes within a 90-day period, this timeline is not routinely maintained. For example, in the third quarter of 2010, drug manufacturers submitted 94 chemistry and manufacturing notifiable changes to Health Canada. Of the 94 submissions, nine met the targeted 90-day deadline.[67] It is not known what the average turnaround time is for notifiable changes, but the potential for them to contribute to drug shortages is apparent.

The backlog of new drug applications awaiting regulatory approval, that could be potential alternatives to drugs in short supply, can also contribute to drug shortages.[20]

Impact of Drug Shortages

The main clinical impacts of drug shortages are felt by patients, pharmacists, and physicians.

Patients

The main concern with drug shortages is that patient care may be compromised.

For drugs with no therapeutic alternative, the lack of drug therapy may lead to poor patient outcomes. Even for drugs that have therapeutic options, patients may experience different or more severe side effects.[2] In some instances, this has led to patients refusing or being unable to take alternative medications.[3]

Patient health outcomes were a concern for 70 per cent of the pharmacist respondents in the 2010 CPhA Drug Shortage survey. From patients' perspectives, the most commonly reported concerns were anxiety, confusion, frustration, and anger, as a result of changes to drug prescriptions and the need for more frequent pharmacist and physician visits.

Drug shortages can potentially create procedure delays, cancellations, and prolonged patient hospital stays.[68] Patients may be forced to pay out-of-pocket if prescribed alternative drugs are not covered by their drug plans[3] or pay higher prices for the alternative.

In addition, changing therapy or the use of a less familiar alternative drug therapy may raise patient safety issues. Findings from the 2010 Institute for Safe Medication Practices survey support this concern. Approximately 35 per cent of the polled pharmacists believed that patients in their facilities had encountered a "near miss" medication error during the past year due to a drug shortage. Roughly 25 per cent reported actual errors, and 20 per cent reported adverse patient outcomes. [19] For example, because of the morphine shortage in the US, two patients died as a result of being prescribed and administered intravenous hydromorphone at the intended dose for morphine.[19] Furthermore, the prevalence of errors and adverse patient outcomes caused by drug shortages is felt to be under-reported.[19]

Pharmacy Services

The main impact of drug shortages on pharmacy services is the amount of time spent by staff repeatedly checking for drugs that are in shortage. Pharmacists are believed to be spending between 30 minutes and three hours per shift sourcing drugs.[3] Some hospital pharmacies have employed dedicated staff specifically to monitor and help resolve supply issues and to research alternative sources and alternative therapies.

Drug shortages divert pharmacists away from spending time on direct patient care. There is

concern that this lack of patient care could potentially lead to lapses in drug use and increases in drug-related problems, especially when an alternative drug is substituted for a drug in shortage.[2] Alternative drugs may require different dosing, preparation, and storage.

There may also be a financial burden associated with alternative drug therapies as they are often more costly to the pharmacy.[69]

Physician Impact

Drug shortages can compromise the quality of patient care. Physicians may be forced to use alternative therapies that are often not supported by evidence-based guidance and may require different prescribing parameters and patient monitoring practices. These new practices require physicians to quickly learn the characteristics and side effects of second, third, and even fourth-line drug therapies and may lead to prescribing errors.

Physicians may also be forced to prioritize patients in order of those with the most urgent need of drugs that are in shortage. When there is only a limited supply of a drug and therapeutic alternatives for specific patient groups are not optimal, physicians will prioritize the drug in limited supply for specific patient groups.[20] For example, during the acyclovir shortage, some hospitals limited the use of acyclovir to confirmed cases of neonatal herpes simplex virus (HSV) meningitis, and used ganciclovir for cases when HSV meningitis was suspected, but not confirmed. [69]

Risk management and liability are also important considerations for physicians who could potentially be accused of providing suboptimal patient care as a result of a drug shortage.

Strategies to Manage Drug Shortages

Proactive strategies are required to help prevent, minimize, and/or manage the impact of drug shortages.

Canadian guidelines for the management of current and future drug shortages have been developed by the CPhA.[1,3] These guidelines include the following recommendations to address drug shortages:

- Prioritize patient needs in the business plans and strategies of all stakeholders in the drug supply chain.
- Expand scopes of responsibility for pharmacists to include adapting new and refill prescriptions and, in collaboration with doctors, to be allowed to substitute equivalent drugs.
- Empower pharmacists to make sure patients are properly managed after drug shortages have been resolved to reduce any risks or safety concerns resulting from substitution of therapy.
- Improve collaboration and communication between drug manufactures and other stakeholders.
- Have government involvement, at the federal and jurisdictional level, to promote an adequate supply of drugs and incentives for manufacturers and wholesalers not to discontinue product lines.
- Create new contractual agreements between provinces, hospitals, and other agencies to ensure that their contracts with manufactures and suppliers include supply guarantee clauses.
- Discourage arbitrage ("the practice of purchasing drugs in one jurisdiction and selling to another").

The CPhA has also developed Assessment and Patient Management Guidelines that include checklists and strategies to help pharmacists manage drug shortages.[3]

US guidelines on drug shortage management have been published by ASHP,[42] instructing pharmacists to validate drug shortages, search for alternatives, investigate implications of compounding products, and educate patients on drug alternatives and costs.[42] Those in charge of health systems are encouraged to conduct a threat analysis and develop contingency plans in advance of a drug shortage.[42] ISMP advocates for the use of risk management strategies, including failure mode and effects analyses, and a discussion of ethical considerations.[70]

Other sources suggest that the FDA expand its authority to require manufactures to (confidentially) notify the FDA when a product has a single-source active pharmaceutical ingredient or supplier, and notify them of planned market withdrawals.[20] To help manage

drug shortages, the FDA has an allocation program in place to limit the distribution of remaining inventory until resolution of the drug shortage.[43]

Guidance to prevent drug shortages in the UK is focused mainly on policies to discourage parallel trading. The UK Department of Health has published guidance papers regarding drug shortages. The enforcement of wholesaler licensing agreements is being more strictly monitored with breaches facing regulatory and/or criminal prosecution.[27] These regulations require the appropriate and continued supply of relevant medicinal products so that the needs of patients in the UK are covered.[27] Manufactures supplying UK wholesalers must verify that the drugs requested are needed by UK patients. Pharmacists and licensed wholesale dealers are encouraged to keep fully documented files of their transactions so that medicinal products in wholesale supply are kept in the licensed distribution chain.[27]

Drug manufacturers represented by the Association of the British Pharmaceutical Industry (ABPI) and the British Generic Manufacturers Association (BGMA) are required to designate one person to deal with supply issues in each company and create written procedures to avoid, identify, and deal with product shortages.[71] Manufacturers are called to take action and curb "inflexibility, enforced by quotas" when managing the UK supply, which is said to have contributed to a situation where demand has surpassed existing supply.[72]

In February 2011, the UK Department of Health issued best practice guidance to ensure the efficient supply and distribution of drugs. The guidance recognizes the importance of regular communication between manufacturers and wholesalers in an effort to increase awareness of supply and demand issues. The creation of contingency plans for the sourcing of supplies for all members of the drug supply chain, regarding supply difficulties, were noted as being of importance. As well, drug prescribers are advised to consider alternative drugs for patients, and encourage patients to request prescriptions for drugs that have been identified as being in shortage as early as possible.[26]

Conclusion

The true causes of Canadian drug shortages are unknown. However, drug shortages are a reality and the causes are believed to be multifactorial. Currently, the Canadian generic drug market is experiencing more shortages than the brand name market. Although drug shortages appear to predate provincial generic price-capping legislation, it is difficult to know to what extent because drug shortages in Canada are currently not routinely or centrally monitored.

Industry mergers and consolidations resulting in single-source products, business decisions to discontinue manufacturing of minimally profitable products, and just-in-time inventory management practices across the supply chain can amplify the effects of drug shortages.

From a policy perspective, an awareness of the different dynamics between the supply chain players and the financial motivations that drive business decisions is critical to an appreciation of the causes of drug shortages and the steps that can be taken to minimize and avoid them.

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Cite as: Morrison A. *Drug Supply Disruptions* [Environmental Scan]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2011.

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CADTH takes sole responsibility for the final form and content of this environmental scan. The statements and conclusions in this environmental scan are those of CADTH.

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Canadian Agency for Drugs and Technologies in Health (CADTH)
600-865 Carling Avenue,
Ottawa, Ontario K1S 5S8

1) is the TPA (Australia) the Therapeutic Drug Agency?

It should be TGA – Therapeutic Goods Administration. It is our equivalent in Australia.

2) Could you provide a few lines to describe the response to the drug shortage proposals in the recent Technical Discussions?

The proposal included a requirement for manufacturers to notify Health Canada of anticipated or occurring drugs shortages when it has a public health impact. This included single source drugs used to treat a serious or life-threatening condition. The proposal also included an authority for the Minister to make this information available through the therapeutic product register.

In general, stakeholders were supportive of the proposal and the policy objective. There were a few consistent themes in the responses:

1) Refinement of scope and trigger

Health Canada needs to clarify the scope or application of the proposal (e.g. all drugs or only those used to treat a serious or life-threatening condition) and the trigger for notification (defining a "shortage").

The industry responses also suggested that the proposal should extend to multi-sourced products to better meet the policy objective and that it must be flexible to accommodate exceptional circumstances, if the trigger for notification includes a set time period.

Health professionals requested for mandatory notification for all drugs, not a defined subset.

2) Mandatory notification and timely communication

Notification of drug shortages should be a mandatory (not in guidance, or voluntary) and Health Canada must ensure timely communication of the information. Not surprisingly, patient/consumer groups and the health professional associations expressed the most obvious support for these conditions.

3) Enforcement measures

There was one explicit reference to fines and penalties as an enforcement measure. However, I think the explicit request for shortage notification to be mandatory, and not voluntary, also suggests the non-industry stakeholders want some assurance that industry will behave responsibly around this, and when they don't we will have appropriate tools to respond.

4) What does HC do with the information that a drug will be discontinued? (which is required to be reported to HC now)

Currently manufacturers are required to notify Health Canada (Minister) within 30 days of discontinuing the sale of a drug in Canada. Once notification is received, Health Canada is obligated to cancel the drug identification number (C.01.014.6).

Once the DIN is cancelled the product's status in the Drug Product Database is updated to "Discontinued (By Company Post-market)". The Drug Product Database is a searchable database available to the public on the Health Canada website. It include information on drugs approved for use in Canada including: name, DIN, company, status, class, route of admin, product monograph etc.

s.21(1)(b)

MinDM follow up re Drug Shortages

Paul Glover to: Leah Canning, Steve Outhouse, Steven Schwendt — 2011-10-03 11:10 AM

Sent by: **Claudia Lafleur**

Cc: Abby Hoffman, Jean Pruneau, Joanne Garrah, Kendal Weber, Anne Lamar, Ken Polk, Sarah Wiles, Victoria Anderson-Selst

Further to Friday's briefing, Joanne Garrah gave CPhA, who chaired the meeting with me, a heads up on our desire to make public ASAP their plan for Drug Shortages. Overall, it went well,

At this point we will leave it to Comms folks to sort out how things are made public.

Kendal and Joanne - can you please update the QP to indicate Minister has received the plan, has reviewed it, and is pleased, as it will pro-actively allow industry to make public/notify of upcoming shortages so that alternate arrangements can be made. It should also indicate final details are being worked out, but industry has committed to make this information publically available later this fall.

We should also work on a reply letter from the Minister ASAP.

Paul

MEDIA LINES

Multi-Stakeholder Working Group on drug shortages

ISSUE: On September 29, 2001 the Multi-Stakeholder Working Group on drug shortages responded to the Minister of Health's call for a plan to proactively alert physicians and Canadians about potential drug shortages. The Working Group – composed of industry and health professional associations – has proposed as a first step the collection and posting of shortage information on two currently live drug shortage web sites http://druginfo.usask/healthcare professional/drug shortages.php and http://vendredipm.wordpress.com It has also committed to the creation of a "one stop shop" drug shortages monitoring system. There will be media interest when this become public

Key Messages on the Working Group Proposal

- Encouraging industry to work to close the information gap on drug shortages for Canadians has been a priority of Health Canada

- Health Canada welcomes the Working Group's proposals. They show that all players have come together to put the health of Canadians and the needs of patients first They confirm that industry is best placed to proactively alert physicians and pharmacists and give them lead time to adjust treatment plans for patients.

- The posting of information on the two proposed drug shortage websites is a good first step in enhancing transparency about shortages to health professionals and Canadians. It will be important to ensure that the sites continue to develop to ensure that broadest possible availability of accurate and useful information.

- The creation of a one stop drug shortage information would be the best way to keep Canadians informed of shortages. And we look forward to the Working Group coming forward with a plan for such a site in early 2012.

- Most importantly we will also continue to press industry to work cooperatively to prevent drug shortages by addressing their root causes.

General Messages on Drug Shortages

- Drug shortages are a global challenge.

- Worldwide shortages of raw materials, manufacturing difficulties, the consolidation of manufacturing into a limited number of global production sites, and global changes in supply or demand are just some of the factors that can affect supply. The ability to resolve a shortage doesn't always rest with one facility, one company or one country.

- Manufacturers know first of supply disruptions and can inform health system professionals fastest, providing lead time to adjust treatment plans. Simply put, industry is best placed to implement ideal solutions.

Fw: Supp B Notes - - DRUGS - SHORTAGES IN CANADA

Joan Kennedy to: HPFB_QP_PPIAD_DGO 2011-11-04 11:48 AM

Cc: Stephanie Priest, Victoria Anderson-Selst, Lara Boulanger-Stewart, Sarah Wiles, Karen Schwerdtfeger, Natalie Racine, Diane Laplante

PPIAD:

Please see questions from ADMO below regarding the DM Drug Shortages Supps B. Note bold text.

Please forward the responses to ADMO as soon as possible.

Collaborating with Canadian Agency for Drugs and Technologies in Health to undertake an environmental scan of the issue. **<Pls provide the expected completion date >**

- Analysis of the pharmaceutical supply chain to better understand the participants, their role, and potentials triggers for supply interruptions. **<When was this analysis conducted? is it ongoing?>**

Thank you.

Joan Kennedy
948-3205
----- Forwarded by Joan Kennedy/HC-SC/GC/CA on 2011-11-04 11:45 AM -----

From: Johane Lefebvre/HC-SC/GC/CA
To: Joan Kennedy/HC-SC/GC/CA@HWC
Cc: Kendal Weber/HC-SC/GC/CA@HWC, Joanne Garrah/HC-SC/GC/CA@HWC
Date: 2011-11-04 08:29 AM
Subject: Supp B Notes - - DRUGS - SHORTAGES IN CANADA

Hello Joan - - Here is the revised version, DG approved. And many thanks for your patience.

DM_Supps B 2011_Drug shortage.doc

Johane

----- Forwarded by Johane Lefebvre/HC-SC/GC/CA on 2011-11-04 08:26 AM -----

Re: Fw: Supps B - Template

Johane Lefebvre to: Johane Lefebvre 2011-11-04 07:25 AM

Cc: Joan Kennedy, Murielle Weiler, Kendal Weber, Joanne Garrah

Hi Joan - - There has been some confusion about this note. Please ignore the attached email. We will send you a revised note asap.

Johane

SUPPLEMENTARY ESTIMATES "B"
DEPUTY MINISTER'S NOTE

TITLE: **Drug Shortages**

BUDGET:

Not applicable

KEY PROGRAM/ISSUE FACTS:

Issue/problem	An increase in drug shortages leading to treatment delays, interruptions, or switches to alternatives
Target population	Health Professionals (physicians and pharmacists) are reported to be experiencing an increase in workload, related to assisting patients in identifying and finding alternatives. Patients with serious illnesses and/or caregivers are experiencing interruptions or delay in treatment due to difficult
Federal action	• Collaborating with CADTH to undertake an environmental scan of the issue. • Analysis of the pharmaceutical supply chain to better understand the participants, their role, and potentials triggers for supply interruptions • Leadership in asking industry to proactively disclose information on drug shortages to health professionals • Leadership in asking industry to work cooperatively to prevent drug shortages by addressing their root causes. • Outreach to health professionals and international regulators to better understand the scope and causes of this issue • Collaboration with the multi-stakeholder working group to identify areas where Health Canada can support their efforts to prevent supply interruptions and market shortages.
Other related information	• Drugs shortages are a global issue affecting most jurisdictions • Variety of causes that lead to drug shortages including: o worldwide shortages of raw materials; o manufacturing difficulties; o the consolidation of manufacturing into a limited number of global production sites; o global changes in supply or demand, and; o natural disasters (Icelandic volcano irruption, earthquake in Japan) • When a pharmacist cannot fill a prescription for an Non-Insured Health Benefits (NIHB) client because of a drug shortage, they normally work with the physician to have the prescription changed or call the NIHB Drug Exception Centre to ask for coverage for the more expensive brand name. In some cases, this means that the NIHB Program approves coverage for a drug that would not normally be approved. • While it is difficult to quantify the actual financial impact on

	the NIHB Program, the Program does not deem it to be significant. Like all drug plans, the NIHB Program is focused on providing clients with access to alternatives where the drugs they are requesting are in shortage. • In December 2010, the Canadian Pharmacists Association reported on the results of a survey of their membership on the issue of drug shortages. In total, 427 pharmacists responded. From those responses, 93% of pharmacists had trouble locating a medication in the previous week, while 70% of pharmacists indicated that patients' health outcomes has been adversely affected. The report also provided recommendations for addressing the issue, including the requirement for more timely and accessible notification of shortages. • In February 2011, the Canadian Medical Association released results from a poll of its members. The results noted that 74 per cent of 743 respondents had faced difficulty getting prescriptions for generic drugs filled. The poll outlined certain consequences of these shortages, including delays in accessing medications, lack of an appropriate alternative, adverse events from alternatives and financial hardship as a result of patients having to purchase more expensive medications • The U.S. has reported a steady increase in the number of reported drug shortages over a 5 year period: 61 shortages (2005) to 178 in 2010. The numbers are expected to be significantly higher for 2011 (>250). The FDA has reported that 178 shortages were prevented in 2010 and 2011 due to early notification by industry.

RESULTS ACHIEVED:

- In March 2011, the Minister wrote to industry and asked they establish a plan to share information on drug shortages. In response to this letter formed a multi-stakeholder working group (WG) with representatives from industry and the health professional associations.

- In September 2011, the WG shared a proposal with Health Canada that outlined a two-phased approach for notification of drug shortages:

    1. Short term solution for notification (December 2011) Posting of information through two existing drug shortage websites (drug name, dosage form, reason for shortage, duration, and date resolved)

    2. Long term solution - creation of a national "one stop" drug shortage monitoring mystem (2012) that would provide notification on drug shortages (current/resolved); and guidance to practitioner on supply chain and clinical management

- The Department is pleased with the proposal and feels it is a good first step in enhancing transparency about shortages to health professionals and Canadians.

- The creation of a "one stop" drug shortage information would be the best way to keep Canadians informed of shortages. And we look forward to the Working Group coming forward with a plan for such a site in early 2012.

GAPS AND CHALLENGES:

- Notification of drug shortages is a good first step that the Department hopes will provide health professionals with the tools they need to better manage drug shortages. However, a long term objective will be to see the number of drug shortages decrease, through improved supply chain management. This is primarily an industry responsibility but may require ongoing federal collaboration and oversight.

- Drug shortages will continue to occur, and will have a public health impact. If industry fails to take on a leadership role, health professionals and patients will continue to look to the federal government to take action to resolve the issue.

Contact:	Joanne Garrah
Telephone Number:	957-6429
Branch:	HPFB
Date:	November 2, 2011

Re: Fw: Drug Shortages
Sarah Wiles to: George Kitchen 2011-11-07 08:12 AM
Cc: Stephanie Priest

Hi George,

Please see below:

- Since the October 7th letter, the Industry led multi-stakeholder working group (WG) has shared a proposal with Health Canada that outlines a two-phased approach for notification of drug shortages:

    1. Short term solution for notification (December 2011) Posting of information through two existing drug shortage websites (drug name, dosage form, reason for shortage, duration, and date resolved)

    2. Long term solution - creation of a national "one stop" drug shortage monitoring system (2012) that would provide notification on drug shortages (current/resolved); and guidance to practitioner on supply chain and clinical management

- The Department is pleased with the proposal and feels it is a good first step in enhancing transparency about shortages to health professionals and Canadians.

Stephanie Priest Can you respond? ...Health Canada... 2011-11-07 07:37:19 AM

From: Stephanie Priest/HC-SC/GC/CA
To: "Miss Sarah Wiles" <sarah.wiles@hc-sc.gc.ca>, "Joanne Garrah" <Joanne.Garrah@hc-sc.gc.ca>
Date: 2011-11-07 07:37 AM
Subject: Fw: Drug Shortages

Can you respond?
...Health Canada...
George Kitchen

----- Original Message -----
From: George Kitchen
Sent: 2011-11-07 07:03 AM EST
To: Stephanie Priest; Steven Schwendt
Subject: Fw: Drug Shortages

See question below. Have we heard any back from the consortium?
Ted Laking

----- Original Message -----
From: Ted Laking
Sent: 2011-11-07 03:38 AM PST
To: George Kitchen
Subject: Drug Shortages

Hey George,

We sent the letter back to the working group on October 7th. Do we have any updates at all? This is an urgent request.

Thanks,

Ted

s.19(1)

Fw: Invitation to a Drug Shortages Roundtable - Nov. 24, 2011

Paul Glover to: Steven Schwendt, Leah Canning, Graham Howell, Stephanie Priest 2011-11-17 09:08 AM

Sent by: Claudia Lafleur

FYI

---- Forwarded by Claudia Lafleur/HC-SC/GC/CA on 2011-11-17 09:07 AM ----

Fw: Invitation to a Drug Shortages Roundtable - Nov. 24, 2011

Joanne Garrah to: Paul Glover, Kendal Weber 2011-11-16 07:53 PM

Cc: Ken Polk

FYI - Sponsored by the Liberal Party.

---- Forwarded by Joanne Garrah/HC-SC/GC/CA on 2011-11-16 07:51 PM ----

From: hedy.fry.a1@parl.gc.ca [mailto:hedy.fry.a1@parl.gc.ca]
Sent: November-14-11 3:02 PM
To:
Subject: Invitation to a Drug Shortages Roundtable - Nov. 24, 2011

November 14, 2011

Over the past two years we have seen the persistent problem of drug shortages develop into an increasingly urgent problem. While there are many factors that contribute to a shortage of a particular drug, it is incumbent upon governments to work with industry, suppliers, other governments, health professionals and experts in order to find solutions, prepare for potential shortages and fund research and development for alternative medications.

For many months, community hospitals and local pharmacies across Canada have experienced significant shortages in prescription drug supplies, including generic drugs, common antibiotics, heart medications, anaesthetics, and cancer-care medications. A recent survey of pharmacists found that over 90 percent of pharmacists face drug shortages each week when filling prescriptions and a similar number noted that these shortages have gotten worse over the past year. These shortages can have significant consequences for patients, delaying or preventing treatment, creating the potential for unintended negative outcomes in patient health, or unexpected financial burdens.

According to health experts, the growing demand for medications in the developing world coupled with unanticipated production issues like shortages of key ingredients – will increase the severity of these shortages unless a plan is put in place to deal with this scarcity.

Managing a serious challenge before it becomes a crisis is not only good stewardship – it's common sense. We must bring together key researchers, industry, physicians and pharmacists so we can develop

short-term recommendations as well as bring forward long-term solutions to address this problem.

The Liberal Party invites you to a roundtable discussion on the issue of drug shortages with Health Critic Hon. Hedy Fry MP, Science and Technology Critic Ted Hsu MP, and Industry Critic Hon. Geoff Regan MP. If you are unable to attend, you are invited to send a representative or suggest another participant.

The roundtable will take place on Thursday, November 24, 2011 from 9:00am to 11:00am in Room 7-50, 131 Queen Street, Ottawa, Ontario.

Please RSVP as soon as possible to Ryan Cotter in Dr. Hedy Fry's office at (613) 992-3213 or hedy.fry.a1@parl.gc.ca.

Thank you and we look forward to working with you to address this important issue.

Sincerely,

Hon. Hedy Fry, P.C., M.P.	Ted Hsu, M.P.	Hon. Geoff Regan, P.C., M.P.
Vancouver Centre	Kingston and the Islands	Halifax West
Liberal Health Critic	Liberal Science & Technology Critic	Liberal Industry Critic

Le 14 novembre 2011

Au cours des deux dernières années, nous avons vu un problème persistent de pénurie de médicaments se transformer en un problème de plus en plus impérieux. Même s'il est vrai que de nombreux facteurs concurrent à la pénurie de certains médicaments, il est du devoir des gouvernements de travailler avec l'industrie, les fournisseurs, d'autres gouvernements, les professionnels et les spécialistes de la santé pour trouver des solutions, se préparer à d'éventuelles ruptures de stocks et financer la recherche et le développement de médicaments de relais.

Partout au pays, des hôpitaux communautaires et des pharmacies de quartier ont dû faire face pendant des mois à d'importantes pénuries de médicaments d'ordonnance, y compris de médicaments génériques, d'antibiotiques courants, d'anesthésiques et de médicaments pour soigner les personnes atteintes de cancer. Une enquête récente menée auprès de pharmaciens a révélé que plus de 90 % des professionnels interrogés sont confrontés à des pénuries de médicaments chaque semaine, lorsqu'ils reçoivent les prescriptions de leurs clients, et autant ont déclaré que ces pénuries s'étaient aggravées au cours de la dernière année. Ce manque de médicaments peut être lourd de conséquences pour les patients, en retardant ou en empêchant les traitements, en ayant des effets négatifs involontaires sur la santé ou en alourdissant indûment les fardeaux financiers.

Selon des spécialistes en santé, l'augmentation de la demande de médicaments dans les pays développés, combinée à des problèmes inattendus de production attribuables à un manque d'ingrédients essentiels, par exemple, entraînera une aggravation de ces pénuries, à moins qu'on mette en œuvre un plan pour parer à cette éventualité.

Il faut gérer ce difficile problème avant qu'il ne se transforme en crise; c'est non seulement une question de bonne gestion, mais aussi de bon sens. Nous devons réunir quelques-uns des plus grands

chercheurs, des représentants de l'industrie, des médecins et des pharmaciens pour mettre au point des recommandations à court terme et aussi pour proposer des solutions à long terme.

Le Pari libéral vous invite donc à une table ronde sur la question des pénuries de médicaments à laquelle assisteront notre porte-parole en matière de santé, la députée Hedy Fry, ainsi que le député Ted Hsu, porte-parole en matière de sciences et de technologies, et le député Geoff Regan, porte-parole en matière d'industrie. S'il vous est impossible d'assister à cette rencontre, vous pouvez envoyer un représentant ou nous proposer le nom d'un autre participant éventuel.

La table ronde se tiendra le jeudi 24 novembre 2011, de 9 heures à 11 heures, dans la salle 7-50, au 131 de la rue Queen, à Ottawa, en Ontario.

Veuillez s'il vous plaît confirmer votre présence dès que possible à Ryan Cotter, au bureau du Dr Hedy Fry, au 613 992-3213 ou à hedy.fry.a1@parl.gc.ca.

Nous vous remercions et nous nous réjouissons d'avance de travailler avec vous pour régler cet important dossier.

Nous vous prions d'agréer, Madame, Monsieur, l'expression de nos sentiments les meilleurs.

Hon. Hedy Fry, C.P., députée	Ted Hsu, député	Hon. Geoff Regan, C.P., député
Vancouver Centre	Kingston et les Îles	Halifax Ouest
Porte-parole libérale en matière de santé	Porte-parole libéral en matière de sciences et de technologies	Porte-parole libéral en matière d'industrie

Drug Shortages e-mail
Sarah Wiles to: Steven Schwendt 2011-11-23 05:30 PM

Hi Steven,

Please find the draft e-mail below. If we move forward with dissemination, I will advise.

Thank you,

Sarah

As you may know, encouraging industry to work to close the information gap on drug shortages for Canadians has been a priority of Health Canada. As such, Minister Aglukkaq asked industry to establish a plan to address drug shortages.

The Minister recently received a plan developed by industry and health care professional associations which was very encouraging. Industry's commitment to post drug shortages information on existing public websites is an important first step to increase transparency on an issue that can have a significant impact on so many Canadians and those who care for them:

http://druginfo.usask/healthcare professional/drug shortages.php; and
http://vendredipm.wordpress.com

Canadians will also be able to view drug shortage information at:
http://www.canadapharma.org/shortage/index.asp?l=en

The Department is very pleased that such a diverse group of stakeholders is acting quickly and is committed to developing solutions on drug shortages to ensure that health practitioners have the tools they need to deliver high quality and patient-focused care to Canadians.

When the first phase of the plan is fully implemented and the creation of the establishment of a national one-stop drug shortages monitoring and reporting system in 2012 is finalized, Health Canada will continue to encourage industry and health care professional associations to collaborate across the health system to develop best practice guidelines for the prevention and management of drug shortages. The goal is to help prevent drug shortages by addressing their root causes.

You will also note that Health Canada has created a Frequently Asked Questions web page for Canadians. These two documents are posted on Health Canada's website (INSERT URLs).

s.21(1)(b)

s.19(1)

Fw: CPhA & Drug Shortages
Lara Boulanger-Stewart to: Natalie Racine 06/12/2011 11:34 AM
Cc: jonathan.loan, Diane Laplante

Hi Nat,

I should have cc'ed you on this request/heads up. Before you action it to PPIAD please see me, as I have been on the phone with George, discussed with Steph, and we just need a short email response back.

Merci
Lara

----- Forwarded by Lara Boulanger-Stewart/HC-SC/GC/CA on 2011-12-06 11:32 AM -----

From: Lara Boulanger-Stewart/HC-SC/GC/CA
To: George Kitchen/HC-SC/GC/CA@HWC
Cc: Stephanie.Priest@hc-sc.gc.ca
Date: 2011-12-06 10:13 AM
Subject: Re: Fw: CPhA & Drug Shortages

Hi George,
All the DGs, ADMs and Steph are in the same mtg until 12pm and then all the HPFB Executives are at the Health Canada EX Forum in Hull from 12:30 to 6pm tonight.

Can you please send the request through the MECS and that way we can action the request and start preparing a response

Thanks
Lara
941-9094

George Kitchen As discussed ----- Original Message ----- 2011-12-06 09:50:04 AM

From: George Kitchen/HC-SC/GC/CA
To: "Lara Boulanger-Stewart" <lara.boulanger-stewart@hc-sc.gc.ca>
Date: 2011-12-06 09:50 AM
Subject: Fw: CPhA & Drug Shortages

As discussed
George Kitchen

----- Original Message -----
From: George Kitchen
Sent: 2011-12-06 07:04 AM EST
To: Stephanie Priest; Steven Schwendt
Subject: CPhA & Drug Shortages

Hello Steph,

Wanted to give you a heads up that [redacted] about the CPhA comments on drug shortages in the media article attached below. Basically they seemed surprised to see a negative comment from Jeff Morrison (e.g , lack of regional details on shortages) considering the organization's role in helping to establish the current coordinated response to the problem.

Can HPFB can provide some context/clarity on his comments. [redacted]

s.19(1)

[redacted]

We can discuss later this morning.
Below is the link and excerpt from the article.

Jeff Morrison, director of government relations and public affairs for the Canadian Pharmacists Association, said the industry, suppliers and have been working on the problem for months. About a week ago, a short-term solution kicked into gear that sees the national brand name and generic drug associations posting alerts of drug shortages on websites in Saskatchewan and Quebec. Through the posts, pharmacists, doctors and even patients can get a warning of what drugs are in short supply. But it doesn't pinpoint where the shortages are geographically. Morrison said the measure is not as robust as the association would like. Part of the problem is awareness, as going to a Saskatchewan website wouldn't be obvious to information seekers in other provinces. As for a long-term monitoring program that also provides help to locate alternative drugs, the pharmacy association said won't fund it because it says it's an industry problem. The industry insists it shouldn't have to carry the entire cost.

(Here is the entire article)
Man with epilepsy fears drug shortage
(The Telegram (St. John's), Barb Sweet, page: A1)
Suivant/More. . (http://206 75.155.80/health/ashow.asp?U=111206/et/11120603.htm&D=3553&A=87)

Health Canada / Santé Canada

Health Products and Food Branch
Direction générale des produits de la santé et des aliments
ACTION REQUEST - DEMANDE D'ACTION
Archived - Archivé

* Number - Numéro: **AR/11-0400**

* MECS No.: **11-123130-530**

* DIRECTORATE - DIRECTION	* ATTENTION
PPIAD/DPPS	**Murielle Weiler, Josh Eckersley, Karla Tate, Johane Lefebvre**

C.C.: **Advisors, ADMO-Correspondence Unit, ADMO-Executive Assistants**

* SUBJECT - OBJET

MO Request - Drug Shortages - Follow-up to comments made by Jeff Morrison from the Canadian Pharmacists Association

* DEADLINE - ÉCHÉANCE	DEADLINE - ÉCHÉANCE
08/12/2011	**02:00 PM**
* REQUESTED FORMAT - FORMAT DEMANDÉ	DATE
E-Mail/Courriel	**06/12/2011**

* REQUEST - DEMANDE

PPIAD (Lead) with Input from SPB, if applicable:

Further to the article attached in the incoming section of the attachments for MECS#11-123130-530 ("Man with epilepsy fears drug shortage"), the Minister's office has requested a short status update with respect to the progress in advancing the coordinated industry response to concerns with respect to drug shortages. The comments (included in the attachments) leave the impression that CPhA has concerns.

Please provide the requested information (informal email response will suffice) to ADMO by 2:00PM on Thursday, December 8, 2011.

PLEASE ADVISE MBU IMMEDIATELY IF:
- ANOTHER EXISTING PRODUCT (QP NOTE, MEDIA LINE, ETC.) CAN RESPOND TO THIS REQUEST,
- THIS REQUEST NEEDS TO BE REDIRECTED TO A DIFFERENT BRANCH/DIRECTORATE or OTHER BRANCHES/DIRECTORATES ALSO NEED TO BE INVOLVED, and/or
- FURTHER CLARIFICATION IS REQUIRED

REQUEST ORIGIN - PROVENANCE DE LA DEMANDE
Minister's Office/Cabinet du ministre

LANGUAGE - LANGUE
English / Anglais

BRANCH CONTACT - AGENT DE LIASON DE LA DIRECTION GÉNÉRALE	TELEPHONE NUMBER - NUMÉRO DE TÉLÉPHONE
Natalie Racine	**(613) 954-1869**

COMMENTS - COMMENTAIRES

Notification History / Historique des avis:

Edit History / Éditions effectuées:

11-123130-530

- Joanne Garrah of HPFB contacted Jeff Morrison of the Canadian Pharmacists Association earlier today on Wednesday, December 7, 2011.

- CPhA's position on the drug shortages plan is consistent with the letter from the Working Group that was sent to the Minister of Health on September 28, 2011. The posting of the drug shortage notifications through the two existing websites is a good first step to improving transparency and supporting better management of drug shortages, but it has some limitations that they would like to see resolved as part of the long term solution.

- CPhA feel it's important to highlight these limitations to maintain interest on this file and ensure implementation of the second phase of the plan.

- The association exists to provide advocacy for their membership - this will influence whether theyare seen publicly as portraying the first step of plan as 'a glass half full or half empty'. The article provides the 'half empty view' of "a positive first step". This may have been a combination of their advocacy role coming through, and reporting perspective.

- As of December 6, 2011, both Rx&D and CGPA were providing input to the Saskatchewan Drug Info Service website. Both are still working on going live with Vendredi PM, the other website.

Created By / Créé par : Natalie Racine/HC-SC/GC/CA

Date Created / Créé le : 2011-12-06 03:26:55 PM

Editor / Éditeur	Edit Date / Date de l'édition
Archive / Archives	2012-01-01 02:16:56 AM
Natalie Racine	2011-12-12 02:47:00 PM
Natalie Racine	2011-12-06 03:40:42 PM

***Only past ten edits are shown**
***Seules les dix dernières mises à jour apparaissent**

Re: Update drug shortages for CMA
Paul Glover to: Kendal Weber 2011-12-12 08:23 AM
Cc: Sarah Wiles, Stephanie Priest

Thanks. I will try can call you during one of the breaks to get a verbal update. Is there a better time?

Kendal Weber Paul - I understand you are joining the Ministe... 2011-12-12 08:11 AM EST

From: Kendal Weber
To: Paul Glover
Cc: Sarah Wiles; Stephanie Priest
Date: 2011-12-12 08:11 AM EST
Subject: Update drug shortages for CMA

Paul - I understand you are joining the Minister in the meeting with the FDA.
We have a little bit of extra info.
OLRM contacted both CMA and US FDA Friday for their positions on Dr. Haggie's recent statement on the US approach for drug shortages. US FDA
While the EO asked FDA to use all appropriate administrative tools to require manufacturers to provide notification, this measure has not led to any regulatory changes. Mainly the FDA sent notices to industry encouraging voluntary notification, which has been successful in leading to more notifications. FDA will keep us appraised of any changes. CMA
Essentially, Dr. Haggie's comments regarding the US is acknowledged by the association, however should be viewed as "one example" to address shortage if the current approach (i.e. voluntary notification and efforts of the external Working Group) are not successful. The association, is pleased with work of the Working Group (as a member), it is a successful move in getting more information voluntarily to healthcare professionals. The association commented that more should be done, an interactive health system website is needed to get information regarding the timing of shortages and alternative solutions (and will depend on how is hosting the website). Also, they feel that while information sharing is good, industry must do more, work closely with HC to address shortage issues. Where HC's oversight may be an issue to a shortage situation, HC take measure to correct, such as expedite review.
K

Health Canada / Santé Canada

Health Products and Food Branch
Direction générale des produits de la santé et des aliments
ACTION REQUEST - DEMANDE D'ACTION
Archived - Archivé

* Number - Numéro: **AR/11-0413**

* MECS No.: **11-123953-35**

* DIRECTORATE - DIRECTION	* ATTENTION
PPIAD/DPPS	**Murielle Weiler, Josh Eckersley, Karla Tate, Johane Lefebvre**

C.C.: **Advisors, ADMO-Correspondence Unit, ADMO-Executive Assistants**

* SUBJECT - OBJET
MO Request - Analysis of U.S. Announcement regarding drug shortages

* DEADLINE - ÉCHÉANCE	DEADLINE - ÉCHÉANCE
19/12/2011	**11:30 AM**
* REQUESTED FORMAT - FORMAT DEMANDÉ	DATE
E-Mail/Courriel	**16/12/2011**

* REQUEST - DEMANDE

Further to the announcement/link below, the Minister's office is requesting that the Department undertake a quick analysis to confirm that the announcement below does not contain any new initiatives and is a reiteration of the policy already put forward by the Obama Administration.

We Can't Wait: Obama Administration makes more progress to reduce, prevent drug shortages (http://www.hhs.gov/news/press/2011pres/12/20111215a.html)

Washington, DC - Today, in response to President Obama's Executive Order of Oct. 31, 2011, the Obama Administration is issuing an interim final rule that will help prevent prescription drug shortages. The rule will require manufacturers that are the only producer of certain critical drugs to report to the Food and Drug Administration all interruptions in manufacturing of products. The rule builds on FDA's current work to ensure Americans have access to the medicine they need.

If possible, please provide the requested information (informal email response will suffice) to ADMO by 11:30AM on Monday, December 19, 2011.

PLEASE ADVISE ADMO IMMEDIATELY IF:
- ANOTHER EXISTING PRODUCT (QP NOTE, MEDIA LINE, ETC.) CAN RESPOND TO THIS REQUEST,
- THIS REQUEST NEEDS TO BE REDIRECTED TO A DIFFERENT BRANCH/DIRECTORATE or OTHER BRANCHES/DIRECTORATES ALSO NEED TO BE INVOLVED, and/or
- FURTHER CLARIFICATION IS REQUIRED

REQUEST ORIGIN - PROVENANCE DE LA DEMANDE
Minister's Office/Cabinet du ministre

LANGUAGE - LANGUE
English / Anglais

BRANCH CONTACT - AGENT DE LIASON DE LA DIRECTION GÉNÉRALE	TELEPHONE NUMBER - NUMÉRO DE TÉLÉPHONE
Natalie Racine	**(613) 954-1869**

COMMENTS - COMMENTAIRES

s.21(1)(b)

Re: Fw: Drug Shortages links
Sarah Wiles to: Jill Watson 2011-12-20 03:54 PM

Hi Jill,

[redacted]

Jill Watson Thanks Sarah. The proposal was shared but do... 2011-12-20 03:53:22 PM

From: Jill Watson/HC-SC/GC/CA
To: Sarah Wiles/HC-SC/GC/CA@HWC
Date: 2011-12-20 03:53 PM
Subject: Re: Fw: Drug Shortages links

Thanks Sarah. [redacted]

Jill Watson
Senior Policy Advisor
Deputy Minister's Office
Health Canada
Telephone: 613-952-1995

Sarah Wiles The Industry led multi-stakeholder working grou... 2011-12-20 03:46:16 PM

From: Sarah Wiles/HC-SC/GC/CA
To: Jill Watson/HC-SC/GC/CA@HWC
Date: 2011-12-20 03:46 PM
Subject: Fw: Drug Shortages links

The Industry led multi-stakeholder working group (WG) shared a proposal with Health Canada that outlines a two-phased approach for notification of drug shortages:

1. Short term solution for notification (December 2011) Posting of information through two existing drug shortage websites (drug name, dosage form, reason for shortage, duration, and date resolved)

2. Long term solution - creation of a national "one stop" drug shortage monitoring system (2012) that would provide notification on drug shortages (current/resolved); and guidance to practitioner on supply chain and clinical management

----- Forwarded by Sarah Wiles/HC-SC/GC/CA on 2011-12-20 02:50 PM -----

From: Sarah Wiles/HC-SC/GC/CA
To: George Kitchen/HC-SC/GC/CA@HWC
Cc: Stephanie Priest/HC-SC/GC/CA@HWC
Date: 2011-11-07 09:11 AM
Subject: Drug Shortages links

Hi George,

As discussed, please find the links for the websites below. Please let us know if you require any further information.

Thank you,

Sarah

RX&D-Drug Shortages' Website
http://www.canadapharma.org/shortage/index.asp

University of Saskatchewan- Saskatchewan Drug Information Services- Drug Shortages Information:
http://www.druginfo.usask.ca/healthcare_professional/drug_shortages.php

DEC 22 2011

FDA's Interim Rule for manufacturer on reporting product discontinuances:

- In response to the executive order issued by President Obama, the FDA has issued an interim final rule (issued December 19, 2011, effective January 18, 2012) that amends the existing post-marketing reporting requirement for manufacturers to notify the FDA 6 months prior to discontinuing a drug that is "life-supporting, life-sustaining or intended for use in the of a debilitating disease or condition".

- Specifically the rule clarifies the term "sole manufacturer" as meaning the only entity currently manufacturing a drug product for sale in the United States, and modifies the definition of "discontinuance" to mean either permanent or temporary.

- The FDA believes that the broader reporting of product discontinuances that will result from these changes will improve the FDA's collection and distribution of drug shortage information to patients and health professionals.

- The rule does reference an enforcement strategy once it comes into effect. However, the executive order directed the FDA to use all available tools to require manufacturers to provide notice of disruptions that could lead to shortages. The new rule expands their scope of authorities in this regard.

- If companies were found to be in contravention of this rule, then it the existing fines and penalties under the US legislation would apply: for first offence, up to one year in prison and up to a $1000 fine; and for second offence, up to 3 years in prison and up to a $10,000 fine.

- The information that is publicly available from the FDA does not speak to challenges with enforcement of the existing provisions, or the proposed enforcement strategy for the amended requirements. The supplementary information included with the final rule (comparable to a Canadian RIAS) indicates that the FDA believes that the clarification of terminology will improve statutory compliance and minimize instances where the manufacturers fail to notify the FDA.

Health Canada's Reaction:

- Health Canada had no prior notice of this announcement, due to the lack of public consultation prior to publication of this interim final rule in the U.S. Federal Register.

- HPFB has contacted the FDA drug shortage office by phone and email to gather more information regarding their compliance and enforcement approach to these requirements. A response is pending.

Reporting Mechanism in Canada for Drug Shortages:

- The Canadian Industry Working Group on Drug Shortages has committed to voluntarily posting drug shortages information on the existing publicly-accessible websites, and to continue to collaborate to establish a national, one-stop drug shortages monitoring and reporting system in 2012. We believe the implementation of this commitment will provide a comparable level of transparency to the US rule, and will meet the same objective of ensuring that notification of drug shortages to patients and health professionals is timely and consistent.

The executive order issued by U.S. President Obama directs the FDA to take 3 steps "to reduce and prevent current and future disruptions in the supply of life-saving medications":

> 1) to use all available tools to require manufacturers to provide advance notice of manufacturing discontinuations that could lead to shortages of products that are life-supporting, life-sustaining or used to treat a debilitating disease;
>
> 2) within the scope of its statutory responsibility to ensure the safety and effectiveness of the drug supply, expand its efforts to expedite regulatory reviews when it would help prevent or mitigate a potential drug shortages;
>
> 3) review certain market behaviours by market participants that have led to stockpiling of drugs in shortage and reselling at higher prices.

In response to the executive order the FDA has issued an interim final rule (issued December 19, 2011, effective January 18, 2012) that amends the existing post-marketing reporting requirement for manufacturers to notify the FDA 6 months prior to discontinuing a drug that is "life-supporting, life-sustaining or intended for use in the of a debilitating disease or condition"

- Specifically the rule clarifies the term "sole manufacturer" as meaning the only entity currently manufacturing a drug product for sale in the United States, and modifies the definition of "discontinuance" to mean either permanent or temporary.
- The FDA believes that the broader reporting of product discontinuances that will result from these changes will improve the FDA's collection and distribution of drug shortage information to patients and health professionals.

① How will they enforce? Penalties/fines?
② Consequences if not complying?

*An interim final rule is a rule adopted without prior public input that can be made effective immediately, but then invites post-promulgation comments. In this case the rule is effective January 18, 2012 and written comments can be submitted until February 17, 2012.

- In the US. there is a statutory authority to promulgate a rule without notice and comment procedures when the agency can demonstrate that notice and public procedure is impracticable, unnecessary or contrary to the public interest.
- There is no equivalent of this type of law-making in Canada. The Food and Drugs Act provides an authority for the Minister to make an interim order but the threshold for making an interim order, and the legislative requirements are more restrictive.

- Indicate our surprise, but this really just clarifies an existing requirement between a rule and requirement)
- How does this compare with the agreement we have from industry?

MECS#11-123130-530

MINISTER'S OFFICE REQUEST

ISSUE:
Further to the article "Man with epilepsy fears drug shortage", the Minister's office has requested a short status update with respect to the progress in advancing the coordinated industry response to concerns with respect to drug shortages. The comments leave the impression that the CPhA has concerns.

RESPONSE:

- HPFB contacted Jeff Morrison of the Canadian Pharmacists Association on Wednesday, December 7, 2011.

- The CPhA's position on the drug shortages plan is consistent with the letter from the Working Group that was sent to the Minister of Health on September 28, 2011. The posting of the drug shortage notifications through the two existing websites is a good first step to improving transparency and supporting better management of drug shortages, but it has some limitations that they would like to see resolved as part of the long term solution.

- The CPhA feels it is important to highlight these limitations to maintain interest on this file and ensure implementation of the second phase of the plan.

- The association exists to provide advocacy for their membership - this will influence whether they are seen publicly as portraying the first step of the plan as "a glass half full or half empty". The article provides the "half empty view" of "a positive first step". This may have been a combination of their advocacy role coming through, and reporting perspective.

- As of December 6, 2011, both Rx&D and Canadian Generic Pharmaceutical Association (CGPA) were providing input to the Saskatchewan Drug Info Service website. Both are still working on going live on *Vendredi PM* (the other website).

Deputy Minister's Office

Branch Head: Paul Glover, ADM, HPFB
Telephone: 613-957-1804

MECS#11-123953-35

MINISTER'S OFFICE REQUEST

ISSUE:

Further to the announcement "We Can't Wait: Obama Administration makes more progress to reduce, prevent drug shortages ", the Minister's office is requesting that the Department undertake a quick analysis to confirm that the announcement does not contain any new initiatives and is a reiteration of the policy already put forward by the Obama Administration.

RESPONSE:

The U.S. Food and Drug Administration's Interim Rule for manufacturer on reporting product discontinuances:

- In response to the executive order issued by President Obama, the FDA has issued an interim final rule (issued December 19, 2011, effective January 18, 2012) that amends the existing post-marketing reporting requirement for manufacturers to notify the FDA 6 months prior to discontinuing a drug that is "life-supporting, life-sustaining or intended for use in a debilitating disease or condition".

- Specifically the rule clarifies the term "sole manufacturer" as meaning the only entity currently manufacturing a drug product for sale in the United States, and modifies the definition of "discontinuance" to mean either permanent or temporary.

- The FDA believes that the broader reporting of product discontinuances that will result from these changes will improve the FDA's collection and distribution of drug shortage information to patients and health professionals.

- The rule does reference an enforcement strategy once it comes into effect. However, the executive order directed the FDA to use all available tools to require manufacturers to provide notice of disruptions that could lead to shortages. This new rule expands their scope of authorities in this regard.

- If companies were found to be in contravention of this rule, then the existing fines and penalties under the US legislation would apply: for first offence, up to one year in prison and up to a $1000 fine; and for second offence, up to 3 years in prison and up to a $10,000 fine.

.../2

- The information that is publicly available from the FDA does not speak to challenges with enforcement of the existing provisions, or the proposed enforcement strategy for the amended requirements. The supplementary information included with the final rule (comparable to a Canadian RIAS) indicates that the FDA believes that the clarification of terminology will improve statutory compliance and minimize instances where the manufacturers fail to notify the FDA.

Health Canada's Reaction:

- Health Canada had no prior notice of this announcement, due to the lack of public consultation prior to publication of this interim final rule in the U.S. Federal Register.

- HPFB has contacted the FDA drug shortage office by phone and email to gather more information regarding their compliance and enforcement approach to these requirements. A response is pending.

Reporting Mechanism in Canada for Drug Shortages:

- The Canadian Industry Working Group on Drug Shortages has committed to voluntarily posting drug shortages information on the existing publicly-accessible websites, and to continue to collaborate to establish a national, one-stop drug shortages monitoring and reporting system in 2012. We believe the implementation of this commitment will provide a comparable level of transparency to the US rule, and will meet the same objective of ensuring that notification of drug shortages to patients and health professionals is timely and consistent.

BACKGROUND INFORMATION

What is an Interim Rule?

- An interim final rule is a rule adopted without prior public input that can be made effective immediately, but then invites post-promulgation comments. In this case the rule is effective January 18, 2012, and written comments can be submitted until February 17, 2012.

- In the US there is a statutory authority to promulgate a rule without notice and comment procedures when the agency can demonstrate that notice and public procedure is impracticable, unnecessary or contrary to the public interest.

.../3

- There is no equivalent of this type of law-making in Canada. The *Food and Drugs Act* provides an authority for the Minister to make an interim order but the threshold for making an interim order, and the legislative requirements are more restrictive.

The Presidential Executive Order:

- The executive order issued by U.S. President Obama directs the FDA to take 3 steps "to reduce and prevent current and future disruptions in the supply of life-saving medications":

  - to use all available tools to require manufacturers to provide advance notice of manufacturing discontinuations that could lead to shortages of products that are life-supporting, life-sustaining or used to treat a debilitating disease;

  - within the scope of its statutory responsibility to ensure the safety and effectiveness of the drug supply, expand its efforts to expedite regulatory reviews when it would help prevent or mitigate potential drug shortages;

  - review certain market behaviours by market participants that have led to stockpiling of drugs in shortage and reselling at higher prices.

Deputy Minister's Office

MECS#11-123953-35

Branch Head: Paul Glover, ADM, HPFB
Telephone: 613-957-1804

FOR A MEETING

11-120243-46

MEMORANDUM TO THE MINISTER OF HEALTH

Meeting with Hedy Fry, the Liberal Health Critic

KEY MESSAGES

- You will be meeting with Ms. Hedy Fry, the Liberal Health Critic, on Thursday November 17, 2011 at 3:15 PM in room 458 of the Confederation Building.
- The purpose of the meeting is to discuss drug shortages and pharmaceutical strategy, health accord negotiations, food and drink labelling and mental health strategy.
- The issues identified for discussion are key topics that have recently appeared in the media and have been raised as concerns by the Liberal Health Critic.

BACKGROUND:

Ms. Hedy Fry, the Liberal Health Critic, has requested a meeting with you to discuss four issues: (1) drug shortages and pharmaceutical strategy; (2) health accord negotiations; (3) food and drink labelling; and (4) mental health strategy. The meeting will take place on November 17, 2011 at 3:15 PM in room 458 of the Confederation Building.

CURRENT STATUS:

Drug Shortages and Pharmaceutical Strategy

Drug shortages are a global challenge. Worldwide shortages of raw materials, manufacturing difficulties, the consolidation of manufacturing into a limited number of global production sites, and global changes in supply or demand are just some of the factors that can affect supply. The ability to resolve a shortage does not always rest with one facility, one company or one country.

In response to this issue, you have written to industry associations requesting voluntary disclosure of information on shortages. On September 29, the Multi-Stakeholder Working Group formed by the Canadian Generic Pharmaceutical Association responded to your call for a plan to proactively alert physicians and Canadians about potential drug

shortages. It also committed to the creation of a "one stop shop" drug shortages monitoring system.

The multi-stakeholder working group is proposing a two stage implementation plan including:

- in the short term, industry will collect drug shortage data from members and drug shortage information will be posted nationally with implementation expected by December 2011; and
- in the longer term, a National Drug Shortage Monitoring System will be created and anticipated for early 2012. Health Canada welcomes the Working Group's proposals.

Please find attached key messages and additional notes in Appendix A.

Health Accord Negotiations

The *Ten Year Plan to Strengthen Health Care* (the 2004 Health Accord) is set to conclude in 2014. The Accord included commitments related to wait times reduction, primary health care reform, health human resources, home care, a National Pharmaceuticals Strategy, access to care in the North, health innovation, public health, accountability commitments and dispute avoidance and resolution. Aboriginal health and Quebec asymmetrical federalism were addressed in separate communiqués.

Cash levels for the Canada Health Transfer (federal funding for health care) tied to the 2004 Health Accord are set in federal legislation up to 2013-2014.

There is growing interest in the federal role in health accord renewal from stakeholders and P/T governments. In the June 2011 Speech from the Throne, the Government of Canada committed to maintaining the 6% escalator while working collaboratively with the P/Ts to renew the Health Accord and continue reducing wait times. It also committed to working with P/Ts to ensure that the health care system is sustainable and that there is accountability for results.

Please find attached key messages and additional notes in Appendix A.

Food and Drink Labelling

Food labelling requirements are regulated under the *Food and Drugs Act*, the *Consumer Packaging and Labelling Act*, and their regulations. These ensure that the information on food labels enables consumers to make informed choices and is truthful and not misleading or deceptive.

Food labelling is an important safety issue for consumers with special nutritional or dietary requirements for those who have allergies or intolerances to certain foods or ingredients. Health Canada amended the *Food and Drug Regulations* on February 16, 2011, to require clear and consistent labelling of priority allergens, gluten sources, and sulphites on pre-packaged food labels. Manufacturers and importers have 18 months from the date of registration of the regulations to adopt the new labelling changes. This means that the new regulations will come into force on August 4, 2012.

The Department has put in place nutrition labelling regulations for most prepackaged foods, set criteria for nutrient content claims and health claims, and is considering improvements to the provision of nutrition information. These include developing a national framework for the consistency of provision of nutrition information in restaurants and foodservices, and improving the consistency of serving sizes in nutrition labelling.

A proposed multifaceted approach to manage caffeinated energy drinks has been developed and posted on Health Canada's Website on October 6, 2011 which includes updated regulatory measures and enhanced labelling requirements to protect the health and safety of Canadians.

Please find attached key messages and additional notes in Appendix A.

Mental Health

The Government of Canada works to help Canadians maintain and improve their mental health and to prevent mental illness. It also recognizes the need for upstream multi-sectoral F/P/T collaboration in the areas of mental health promotion and mental illness prevention in areas of shared jurisdictions.

Recent high profile and tragic events have brought heightened national attention to the issue of suicide prevention. Suicide in Canada is a complex and costly cause of death that disproportionately affects certain at-risk sub-populations. In 2007, the suicide rate was 11 per 100,000 people, making it the 10th leading cause of death.

Several provinces have developed or are currently developing their own strategies to improve the mental health of their citizens and prevent the mental illness. The Mental Health Commission of Canada (MHCC) is currently developing a Mental Health Strategy for Canada planned to be released at the beginning of 2012.

In October 2011, the Bill C-300 was introduced in the House of Commons calling for the development of a Federal Framework for Suicide Prevention. Suicide prevention will also be discussed by Health Ministers at the upcoming Health Minister's Meeting.

The release of the MHCC's Strategy as well as the discussions generated by the Bill C-300 will inform the options for collaboration on mental health, including an approach for suicide prevention.

Please find attached key messages and additional notes in Appendix A.

PORTFOLIO CONSIDERATIONS:
N/A

NEXT STEPS:
This meeting presents an opportunity to share progress in current initiatives related to drug shortages and pharmaceutical strategy, health accord negotiations, food and drink labelling and mental health strategy with Ms. Fry. It also provides an opportunity to learn about Ms. Fry's ideas and concerns regarding these issues.

Assistant Deputy Minister

MECS # 11-120243-46

Branch Head: Abby Hoffman
Telephone: 946-1791

Attachments
Appendix A - Key Messages and Additional Notes

Document created on:

Appendix A

Key Messages and Additional Notes

Drug Shortages and Pharmaceutical Strategy

- Drug shortages are a global challenge. The ability to resolve a shortage does not always rest with one facility, one company or one country. Manufacturers are the first to know of supply disruptions and can inform health system professionals fastest, providing lead time to adjust treatment plans.

- In response to the Minister's request for voluntary disclosure of information, the Canadian Generic Pharmaceutical Association established a multi-stakeholder working group to discuss how shortages information could be collected and shared.

- On September 29, the Multi-Stakeholder Working Group proposed a two stage implementation plan.

- In the short term, industry will collect drug shortage data from members and drug shortage information will be posted nationally with implementation expected by December 2011. In the longer, term a National Drug Shortage Monitoring System will be created and anticipated for early 2012.

- Health Canada welcomes the Working Group's proposals.

Health Accord Negotiations

- The Government of Canada is committed to a universal, publicly-funded health care system and the Canada Health Act.

- Since 2004, we have worked collaboratively with provinces and territories to advance the objectives of the 2004 Accord and have introduced new measures to reduce wait times, improve access to physicians and nurses, and act on key public health concerns like childhood obesity.

- While no timeline has yet been established for formal discussions, the Government is committed to Health Accord renewal with a focus on accountability and results for Canadians while respecting provincial-territorial jurisdiction.

- Federal funding for health care through the Canada Health Transfer is legislated to grow by 6% annually until 2013/2014, and we are committed to extending this arrangement.

- We are still two and a half years away from the conclusion of the 2004 health accord, which provides ample time to engage with our provincial and territorial partners on accord renewal.

Food and Drug Labelling

General Comments

- The priority of the Government of Canada is the health and safety of Canadians when it comes to ensuring useful and understandable nutrition and other health-related information on food labels.

- Clear uniform information on food labels can support consumers in making informed food choices. One example of this is the Nutrition Facts table (NFt) which is mandatory on the labels of most prepackaged foods. The Nutrition Labelling regulations specify requirements for the NFt to ensure that it is accessible, legible and consistent on all labels. The information on the NFt can be used to choose products and to compare products for a healthier food choice.

- Health Canada is currently working with provincial and territorial government partners and other stakeholders to develop a national framework for the consistency of provision of nutrition information in restaurants and food services.

- Health Canada is also preparing to hold broad public consultations on a series of potential amendments related to serving sizes, nutrients in the NFt, and Daily Values for nutrients (including sodium). A performance evaluation of the nutrition labelling regulations is also being planned.

- The Food and Drug Regulations control nutrient content claims such as "fat-free" or "low in saturated fat" to ensure they are based on standard, meaningful criteria and use consistent language.

- Health Canada has set out clear guidelines for industry on the nature of the evidence they must have to support their claims. Where a food carries a claim linking the food or a nutrient in the food to a serious disease such as heart disease or to cholesterol lowering, the criteria that a food must meet and the wording that

must be used are set out in the Food and Drug Regulations or published on the Health Canada website.

- With nutrition labelling and regulations governing health and nutrient claims, Canadians have the tools to make healthy food choices when they shop for groceries.

Labelling

- Health Canada amended the *Food and Drug Regulations* on February 16, 2011, to require clear and consistent labelling of priority allergens, gluten sources, and sulphites on pre-packaged food labels.

- Manufacturers and importers have 18 months from the date of registration of the regulations to adopt the new labelling changes. This means that the new regulations will come into force on August 4, 2012.

- During this transition period, Canadians continue to be advised that the absence of a declaration of any of the priority allergens, gluten sources or sulphites will not necessarily mean that these substances are not part of the product ingredients. This is because the old labelling requirements will be in placed until August 4, 2012, and as such, their possible presence could be "hidden". During the transition period, the same level of vigilance as before should be applied by consumers when reading food labels.

- Health Canada will continue to work towards improving the labelling requirements for food colours.

Energy Drinks

- Health Canada has identified a number of measures to mitigate the potential risks associated with the over consumption of energy drinks which include the establishment of regulatory labelling requirements.

- In addition to the current food labelling provisions such as ingredient labelling, nutrition facts panel, allergen labelling, etc., Health Canada proposes the following additional labelling information requirements:
  - the amount of caffeine from all sources in mg per container or serving size;
  - A statement on the label identifying the product as a "high source of caffeine" given that an energy drink will be required to contain a minimum

amount of caffeine that is seemed to be sufficiently high;
- A statement indicating that the product is "Not recommended for children, pregnant/breastfeeding women, individual sensitive to caffeine"; and
- The statement "Do not mix with alcohol".

- Depending on the formulation of the product, additional labelling requirements may be required. The proposed new labelling requirements by the Department will help Canadians make informed decisions about these products, reducing the chances of over consumption of caffeine and other ingredients such as vitamins.

Mental Health

- Several provinces have developed or are currently developing their own strategies to improve the mental health of their citizens and prevent the mental illness. The Mental Health Commission of Canada (MHCC) is currently developing a Mental Health Strategy for Canada planned to be released at the beginning of 2012.

- In October 2011, the Bill C-300 was introduced in the House of Commons calling for the development of a Federal Framework for Suicide Prevention.

- The release of the MHCC's Strategy as well as the discussions generated by the Bill C-300 will inform the options for collaboration on mental health, including an approach for suicide prevention.

- Greater F/P/T collaboration in the area of mental health promotion and mental illness prevention, including suicide prevention given that suicide is an important public health issue that requires partnerships between all levels of government, NGOs, the private sector, communities, families and individuals.

<u>Federal Initiatives for Mental Health</u>

- The Government of Canada invests in a number of initiatives including mental health-related research and knowledge development, and programs designed to build positive mental health and address the underlying factors that can affect mental health and suicide. Recently the Public Health Agency of Canada announced an investment of $27 million in mental health initiatives that will reach children, youth and their families in over 50 Canadian communities.
- Additionally, $110M over 5 years was committed in 2008 to undertake research demonstration projects in the area of mental health and homelessness.
- The federal government invested $130 million in funding over 10 years to

establish and support the Mental Health Commission of Canada to undertake a number of key initiatives including the development of a Mental Health Strategy for Canada, a Knowledge Exchange Centre and an anti-stigma campaign entitled Opening Minds.

Federal Initiatives for Suicide Prevention

- The Public Health Agency of Canada is investing over $114M annually in programs to support healthy childhood development, with a focus on vulnerable families and those living in higher-risk conditions. Three federally funded programs, the Community Action Program for Children, the Aboriginal Head Start in Urban and Northern Communities, and the Canadian Prenatal Nutrition Program all support early childhood development in hundreds of communities across Canada. These programs reach over 100,000 participants every year.
- The Public Health Agency of Canada provides $7M of funding annually for the Family Violence Initiative to increase awareness, undertake research and better respond to this problem in Canada. Through this initiative, 15 federal departments and agencies collaborate to help address such issues as emotional, physical and sexual abuse.
- Since 2006, the Government of Canada, through the Canadian Institutes of Health Research, has invested over $290 million in research on mental health and addiction, including $6 million on research into suicide prevention and its risk factors in 2009-10 alone.
- In June 2011, the Government of Canada announced an investment of $27 million, over the next four years, through the Public Health Agency of Canada's Innovation Strategy to support nine large-scale mental health promotion initiatives for children, youth and families across the country. The initiatives are focused on improving the mental health of children, youth, and families.
- The Government of Canada provided $75 million until 2015 to expand the National Aboriginal Youth Suicide Prevention Strategy which is a collaborative strategy promoting the protective elements and the reduction of risk factors for Aboriginal youth suicide, including the development of new knowledge and best practices on suicide prevention.

Speech for [Insert Name]

Drug Shortages
House of Commons
Parliament Hill, Ottawa

Mister Speaker,

I rise today to congratulate the Minister of Health for taking a leadership role with respect to drug shortages. Her leadership is putting the needs of Canadian patients first.

Her Department is doing their part to help minimize the impact of shortages felt by Canadians and their health care practitioners. In fact, Health Canada is helping health professionals get access to currently unauthorized drugs through the Department's Special Access Programme and speeding up consideration of new product applications, as well as requests to change existing products and to use new production facilities.

Health Canada is helping health professionals get access to currently unauthorized drugs through the Department's Special Access Programme. Health Canada is also speeding up consideration of new product applications as well as requests to change existing products and to use new production facilities.

In addition to these actions, encouraging industry to work to close the information gap on drug shortages for Canadians has been a priority of Minister Aglukkaq.

This priority will help ensure that Canadians are better informed on shortages so that they have time to plan and change treatments if necessary. This work is now a reality with the posting of drug shortages information on existing public websites.

Let's be clear that this would not have been made possible if it had not been for the Minister of Health's call for a plan to proactively alert physicians and Canadians about potential drug shortages.

By working together with industry, our progress will lead to the development of a national, one-stop drug shortages monitoring and reporting system in early 2012.

Mister Speaker, our government is pleased by the good corporate citizenship that manufacturers have shown. However we also believe that more can be done to address the root causes of dug shortages so they happen less often.

In closing, drug shortages are not unique to a specific country but a global challenge and Canadians can be proud that our government is working with governments around the world and industry draw on experiences that will help alleviate uncertainty and anxiety felt by patients and health care providers when they suddenly discover that needed medications are in shortage or not available at all.

Thank you.

Speech for [Insert Name]

Drug Shortages
House of Commons
Parliament Hill, Ottawa
Date:

Mister Speaker,

Our government understands the uncertainty and anxiety felt by Canadians and health care providers when they suddenly discover that needed medications are in shortage or not available at all.

As manufacturers know first of supply disruptions, they are able to inform health system professionals fastest, providing lead time to adjust treatment plans. Simply put, industry is best placed to implement practical solutions.

This is why earlier this year, Mr. Speaker, my colleague, the Minister of Health has encouraged industry to work with health care professionals to close the information gap on drug shortages for Canadians.

At the end of September, Minister Aglukkaq received a plan developed by industry and health care professional associations which was very encouraging.

Our government is pleased that industry's commitment to now post drug shortages information on existing public websites. This is an important first step to increase transparency on an issue that can have a significant impact on so many Canadians and those who care for them.

In fact, having information about what drugs may be in shortage is in everyone's best interest. Canadians and their doctors will now be better informed on shortages so that they have time to plan and change treatments, if necessary.

But Mr. Speaker, we will not rest because more can be done and will be done. I am encouraged by the good corporate citizenship that manufacturers have shown in making these pledges, including developing a plan for a

national, one-stop drug shortages monitoring and reporting system in early 2012.

In closing Mister Speaker, let's be clear about one thing: our top priority is putting the needs of patients first.

Thank you.

Speech for [Insert Name]

Drug Shortages
House of Commons
Parliament Hill, Ottawa

Mister Speaker,

Drug shortages are not unique to Canada but a global challenge to all health regulators. I note that in late-October, President Obama directed the U.S. FDA to take actions that are quite similar to those are already taking in Canada.

In fact, my colleague, the Minister of Health has taken a leadership role in the world. Earlier this year, Minister Aglukkaq told the drug companies that if they did not take action, our government would look to regulations to require action.

This is not because our government does not want to work with industry, but as we all know, industry is responsible for understanding the supply needs for their products and taking steps to prevent supply interruptions.

Our government is pleased to report to the House that these companies have responded positively to the Minister's request. The uncertainty and anxiety felt by Canadians and health care providers will soon give way to having information about what drugs may be in shortage so that they have time to plan and change treatments.

The posting of drug shortages information on existing public websites is due to the leadership shown by our government and industry working together. Our pledge to continue working together will lead to the development of a national, one-stop drug shortages monitoring and reporting system in early 2012.

In closing Mister Speaker, our government will continue to consult with our international regulatory counterparts, including the US Food and Drug Administration, to assess the problem in other countries and the response being taken or considered. Make no mistake about it: our actions and leadership will help alleviate the issue of drug shortages in Canada.

Thank you.

FINAL

MEDIA LINES
European Medicines Agency (EMA) regulatory action re: Ben Venue Laboratories

ISSUE: In Europe, a recall is being initiated for Busilvex (cancer drug used in combination with other chemotherapeutic agents and/or radiotherapy), Velcade (cancer drug used in the treatment of multiple myeloma and mantle cell lymphoma), and Vidaza (cancer drug: antineoplastic drug used in chemotherapy to kill cancer cells) from Ben Venue Laboratories, located in Bedford, Ohio, U.S. Ben Venue Laboratories has issued a press release regarding their manufacturing status indicating that they have voluntarily and temporarily suspended manufacture and distribution of products produced in its Bedford facility.

[**NOTE TO MEDIA RELATIONS**: There are currently approved media lines re: Health Canada Notice to Hospitals re: Ben Venue Laboratories in the database that can also be used for any potential media interest.]

KEY MESSAGES:

- Health Canada is aware that the European Medicines Agency is taking regulatory action following the joint inspection of Ben Venue Laboratories by the health authorities of France, the United Kingdom and the United States.

- In Europe, a recall is being initiated for lots of Busilvex, Velcade, and Vidaza from Ben Venue Laboratories.

- Canadians are not affected by the recall of Busilvex (aka Busulfex in Canada), Vidaza, and Velcade as alternative manufacturers are supplying the Canadian market.

- International Regulators and Canada are continuing to allow the importation of Caelyx from Ben Venue Laboratories as there are no alternative suppliers and the health benefits of this drug outweigh the risk associated with the quality concerns.

Q. Will the European recall impact drugs bound for the Canadian market?

No. It is important to note that Busilvex (aka Busulfex in Canada), Vidaza, and Velcade are no longer supplied by Ben Venue Laboratories as alternative manufacturers are supplying the Canadian market.

Q. Will Health Canada follow the EMA and recall products from Ben Venue Laboratories?

In Canada, Busilvex (aka Busulfex in Canada), Vidaza, and Velcade are no longer supplied by Ben Venue Laboratories as alternative manufacturers are supplying the Canadian market.

However, should Health Canada identify a risk to health associated with any of the drugs being imported from Ben Venue Laboratories, we will take immediate and appropriate action.

International Regulators and Canada are continuing to allow the importation of Caelyx from Ben Venue Laboratories as there are no alternative suppliers and health benefits of this drug outweigh the risk associated with the quality concerns

Q. Will the voluntary and temporary suspension of the Ben Venue Laboratories at the Bedford facility affect drugs destined for the Canadian market?

The voluntary and temporary suspension of the Ben Venue Laboratories at the Bedford facility could affect the supply of medically necessary drugs imported into Canada. Health Canada continues to work actively with international partners to minimize the impacts of shortages, if and when they occur.

A Notice to Hospitals was issued in August 2011 to let health professionals know about these issues so that they can factor potential changes in supply for certain drugs into their patient-care decisions. The Notice to Hospitals is available on the Health Canada website: http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2011/ben_ven_nth-aah-eng.php

Health Canada does not anticipate that patients will be severely affected by shortages of non medically necessary drugs should they occur, as either alternatives are readily available for these drugs or the conditions they are used to treat are not considered serious/life threatening.

Prepared by: Johanne Veenstra, Inspectorate
Revised by: Aldège Bellefeuille, Communications
Reviewed by Stephanie Reid, Inspectorate

Approved by:
Basanti Ghosh, Director, HPFBI, (November 22, 2011)
Diana Dowthwaite, DG, HPFBI, (November 23, 2011)
Legal, (pending)
Ken Polk, Comms Exec, (November 23, 2011)
Sophie Galarneau, Director, Public Affairs, (November 23, 2011)
Charles Mojsej, DG, SCD (Nov. 23, 2011)
Paul Glover, ADM, HPFB, (November 23, 2011)
Anne Lamar, ADM, PACCB, (FYI)
DMO (FYI)
MO (Nov 24)
PCO (FYI)

FINAL
November 25, 2011

MEDIA LINES
Supply and Safety Update on CAELYX

ISSUE: On November 25, 2011 Janssen Inc. issued a Dear Healthcare Professional Letter advising that they are anticipating that their existing inventory of CAELYX will be depleted by early December. In this updated DHPL, Janssen reiterates that CAELYX, a cancer drug imported into Canada from Ben Venue Laboratories, should only be used to continue treatments that have been initiated and that no new patients should be initiated on this drug until further notice. Of note, this is the same advice given by the EMA in their press release.

[**NOTE TO MEDIA RELATIONS**: There are currently approved media lines re: Health Canada Notice to Hospitals re: Ben Venue Laboratories & EMA recall of Ben Venue Laboratories products in the database that can also be used for any potential media interest.]

KEY MESSAGES:

- On Aug 17, 2011, Health Canada issued a Notice to Hospitals advising of potential supply shortages for certain drugs being manufactured by Ben Venue Laboratories, including Caelyx.

- Over the past few months, Janssen Inc. has been regularly communicating updates on the supply issue of CAELYX to health care practitioners in Canada.

- In light of the deterioration to the supply shortage of CAELYX in Canada, Janssen Inc is advising health care practitioners that it should only be considered for absolutely essential use, to meet the clinical needs of patients already part-way through a course of treatment.

Q. Why is Janssen Inc experiencing supply issues with CAELYX?

According to the company, this shortage is due to production difficulties experienced by their contract manufacturer, Ben Venue Laboratories. Health Canada advised health care professionals of a potential supply shortage and concerns with the quality of CAELYX. (NtH sent on August 17 and web-posted August 18).

Comment [J1]: http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2011/ben_ven_nth-aah-eng.php

Q. Is Canada the only country experiencing supply issues with CAELYX?

No. Other countries, including the U.S. and Europe, are experiencing supply issues regarding CAELYX due to Ben Venue Laboratories voluntary decision to temporarily suspend manufacturing and distribution of drug products, including CAELYX. Ben Venue Laboratories has issued a press release regarding their manufacturing status.

Comment [A2]: http://www.benvenue.com/pages/release.html

Q. What is Health Canada doing given the situation with Ben Venue Laboratories and drug shortage issues?

Recognizing drug shortages as a global issue, Health Canada has consulted with and will continue to consult with international regulatory counterparts, including the US Food and Drug Administration, the EMA and TGA, to assess the problem in other countries and the response being taken or considered.

In the circumstance with Ben Venue Laboratories, Health Canada has put in place controls which include the increased oversight of the site/products through collaboration with Ben Venue Laboratories, the Canadian importers and Health Canada's international regulatory partners.

Ben Venue Laboratories has also committed to carrying out improvements to its facility in order to rectify the identified quality deficiencies. Health Canada will continue to monitor closely the activities of Ben Venue Laboratories and the products being imported from this site, in an effort to minimize risk to the health of Canadians, while at the same time allowing to the extent possible, uninterrupted access to these medically necessary drugs in Canada.

Q. If the inventory of CAELYX is depleted by December, are there alternatives for Canadian patients?

A. Given that Caelyx is used in complex cancer therapy, there may be other alternative treatments to CAELYX available for patients in Canada. Health Canada recommends that patients consult with their health care providers about alternative treatments and which is most appropriate in their situation.

Prepared by: Aldège Bellefeuille, Communications
Reviewed by: Johanne Veenstra, Inspectorate and Susan Robertson, TPD

Approved by:
Barbara J. Sabourin, A/DG, TPD, (November 24, 2011)
Diana Dowthwaite, DG, Inspectorate, (November 24, 2011)
Nancy Othmer, Legal, (November 24, 2011)
Ken Polk, Comms Exec, (November 24, 2011)
Sophie Galarneau, Director, Public Affairs, (November 24, 2011)
Paul Glover, ADM, HPFB, (November 25, 2011)
Anne Lamar, ADM, PACCB, (November 25, 2011)
DMO (November 25, 2011)
MO (November 25, 2011)
PCO (FYI)

Web info sheet on Drug Shortages

How is Health Canada working with the industry to address drug shortages?

Encouraging industry to work to close the information gap on drug shortages for Canadians has been a priority of Health Canada.

In March 2011, the Minister of Health wrote to drug product industry associations, encouraging them to work with health care and pharmacy stakeholders to find solutions to improve the current situation.

The ability to provide better information on supply disruptions to health care institutions and professionals exists within the hands of manufacturers working together with whom they supply.

At the end of September 2011, Minister Aglukkaq received a plan developed by industry and health care professional associations which was very encouraging. Industry is committed to posting drug shortages information on existing public websites. This is an important first step to increase transparency on an issue that can have a significant impact on so many Canadians and those who care for them.

http://druginfo.usask/healthcare professional/drug shortages.php and http://vendredipm.wordpress.com. Canadians will also be able to view drug shortage information at: http://www.canadapharma.org/shortage/index.asp?l=en

Health Canada encourages industry and health care professional associations to continue to collaborate to establish a national, one-stop drug shortages monitoring and reporting system in 2012. Health Canada will also continue to look to industry to work cooperatively to prevent drug shortages by addressing their root causes.

What causes drug shortages?

Drug shortages are a global challenge. Shortages are temporary supply interruptions that can have a variety of causes. These include:

- a manufacturer removing one of their products from the market;
- a mishap, such as a mass product loss in shipping;
- a company needing to pause production to make manufacturing improvements in order to meet quality standards; and
- worldwide shortages of raw materials needed to make a certain product.

What is the Federal Government's role?

Health Canada is responsible to help ensure that products sold on the Canadian market meet high standards with respect to safety, efficacy and quality.

In circumstances where shortages of important drugs do occur, Health Canada will work with manufacturers and health professionals to minimize the impacts of drug shortages. Our work includes providing access to alternatives on an emergency basis, working with companies to resolve manufacturing and quality issues, and expediting review to support manufacturing changes or new suppliers.

Recognizing this as a global issue, Health Canada has consulted with and will continue to consult with international regulatory counterparts, including the US Food and Drug Administration, to assess the problem in other countries and the response being taken or considered.

What should happen to lessen the impact of shortages and meet patient needs?

Drugs are manufactured and supplied by industry. As such, manufacturers are in the best position to understand the demands for their product and to anticipate any potential shortages. These websites provide another way for industry to notify health care professionals of any issues that could lead to a shortage.

The sooner health care institutions and health care practitioners are informed about a coming supply disruption, the sooner they can make arrangements to:

- locate surplus supplies held by counterparts;
- decide on alternative medication(s) available on the market; and/or
- ration existing supplies for greatest needs.

These actions can help ensure critical therapies for serious conditions are uninterrupted for patients.

What is Industry doing about drug shortages?

Industry is now directly reporting drug shortage information to two drug shortage websites:
http://druginfo.usask/healthcare professional/drug shortages.php
http://vendredipm.wordpress.com.

Canadians will also be able to view drug shortage information at:
http://www.canadapharma.org/shortage/index.asp?l=en

The posting of information on drug shortage websites is a good first step in enhancing transparency about shortages to health professionals and Canadians.

Why doesn't Health Canada force companies to make drugs available to meet patient needs?

Drug products are manufactured and supplied by industry. Health Canada has a broad authority with respect to the sale of drugs in Canada to help ensure that they meet high standards with respect to safety, efficacy and quality. This authority does not extend to forcing companies to bring a product to the Canadian market or maintaining sufficient supplies to meet the needs of patients. These are business decisions and are the responsibility of industry.

If I can't get a drug, who should I contact?

Canadians should speak to their healthcare practitioner regarding any questions or concerns about health products that may be in shortage or potential alternatives. They may also wish to directly contact the product manufacturer, who will be the first to know about potential supply disruptions.

Canadians may also wish to visit the following web sites to determine if a specific product has been identified in shortage:

http://druginfo.usask/healthcare professional/drug shortages.php and http://vendredipm.wordpress.com.

Canadians will also be able to view drug shortage information at:

http://www.canadapharma.org/shortage/index.asp?l=en

Prepared by:
Aldège Bellefeuille, Communications
Reviewed by: Joanne Garrah, PPIAD

Approved by:
Kendal Weber, DG, PPIAD, (November 17, 2011)
Nancy Othmer, Legal Services, (November 18, 2011)
David Gotlieb for Ken Polk, Communications Executive, (November 18, 2011)
Sophie Galarneau, Director, Public Affairs (Nov 18)
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MO, (Nov 23)

Communications Approach

Enhanced Communications Presence on Drug Shortages

Issue: Shortages of medically necessary drugs continue to attract public attention. Ongoing stakeholder concerns and increased parliamentary engagement make it necessary for Health Canada to communicate more clearly on the role it plays on shortages and what it has done to date to facilitate increased transparency from drug companies.

Key Messages

- Drug shortages are not unique to a specific country but a global challenge that requires a collaborative effort by all players to put the health of patients first.
- Encouraging industry to work to close the information gap on drug shortages for Canadians has been a priority of Health Canada.
- In March 2011, the Minister of Health wrote to drug product industry associations, encouraging them to work with health care and pharmacy stakeholders to find solutions to improve the current situation.
- The ability to provide better information on supply disruptions to health care institutions and professionals exists within the hands of manufacturers working together with whom they supply.
- At the end of September 2011, Minister Aglukkaq received a plan developed by industry and health care professional associations which was very encouraging. Industry is committed to posting drug shortages information on existing public websites.
- This is an important first step to increase transparency on an issue that can have a significant impact on so many Canadians and those who care for them.
- Given the complex, global issue of drug shortages, Health Canada has posted a web fact sheet that will provide Canadians and stakeholders with pertinent drug shortage information, including web sites that identify which medications are currently in shortage.
    - This information can be found at the following websites:
        - http://druginfo.usask.ca/healthcare_professional/drug_shortages.php
        - http://vendredipm.wordpress.com/
- More work needs to be done and will be done regarding drug shortages, but Canadians can be confident that all players have come together to put the health and needs of patients first.
- Health Canada encourages industry and health care professional associations to continue to collaborate to establish a national, one-stop drug shortages monitoring and reporting system in 2012.

COMMUNICATIONS APPROACH:

The communications approach recommended is medium-profile and proactive.

Target Audiences:

- Stakeholders (Medical institutions, health care practitioners, drug industry) associations, and patient advocacy groups
- Parliamentarians
- Media
- General public

Communications/Stakeholder Outreach Products/Activities

- Web Fact Sheet (FAQs) (Completed)
- Ministerial Web statement (In development.)
- HPFB-ADM Email to stakeholders (To be completed November 24)
- HPFB ADM to discuss matter at meeting with Patient Consumer Pool. (December 7)
- Social media monitoring (TBD)

Potential Additional Communications/Stakeholder Outreach Activities

- Joint ministerial/industry/pharmacists event around the launch of the interim drug shortage information websites. December 2011

- Joint ministerial/industry/pharmacists event around the launch of single drug shortage information website (2012 – pending receipt of plan from industry and clear timelines for completion.

- Briefings for parliamentarians (TBC)

- Briefings for targeted patient groups by HPFB (TBC)

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DMO (Dec 5, 2011)
MO (Dec 7, 2011)

FINAL
December 14, 2011

HOLDING LINES
EMA News Release re: Quality Assurance at Ben Venue Laboratories

ISSUE: In Europe, a recall is being initiated as a precautionary measure for the antifungal Ecalta and the diagnostic medicine Luminity from Ben Venue Laboratories. The EMA is also providing recommendations to healthcare professionals in Europe to inspect the vials of Ceplene and Torisel in order to exclude any potential presence of particles before administration. Celpene is not on the Canadian market. The Press Release was published on the European Medicines Agency website on Friday December 9, 2011. Given that this is Ben Venue related coupled with recalled health products, there could be media interest.

KEY MESSAGES:

- Health Canada is aware of the European Medicines Agency's recall of certain lots of the anti-fungal products Ecalta (aka Eraxis in Canada) and Luminity (aka Definity in Canada). Health Canada is also aware of their recommendations to European healthcare professionals to inspect the vials of Ceplene and Torisel.

- Ecalta is no longer imported to Canada from Ben Venue Laboratories. An alternative manufacturer is supplying the Canadian market. Celpene is also not available on the Canadian market.

- Like other countries, Canada is continuing to allow the importation of Definity and Torisel from Ben Venue Laboratories. There are no alternative suppliers and the health benefits of these drugs outweigh the risk associated with the continued use of these products.

- Canadians can be confident that if a risk to health is identified by Health Canada, immediate and appropriate action will be taken to help protect the health and safety of Canadians.

What are Definity and Torisel used for?

Definity is administered intravenously for ultrasounds regarding heart, liver and kidneys. It is an ultrasound contrast imaging agent that is indicated for use in contrast-enhanced ultrasound imaging of the heart in adults when the image obtained with non-contrast echocardiography is not optimal. It is also indicated for use in contrast-enhanced ultrasound imaging of the liver and kidney.

Torisel is administered intravenously used in the treatment of cancer of the kidney. The product information includes recommendations for use of a filter for the administration of this product, which will help to mitigate the risk of injection of particulate matter.

Are these drugs facing supply issues in Canada?

The voluntary and temporary suspension of the Ben Venue Laboratories at the Bedford facility could affect the supply of medically necessary drugs imported into Canada. Health Canada continues to work actively with international partners to minimize the impacts of shortages, if and when they occur.

A Notice to Hospitals was issued in August 2011 to let health professionals know about these issues so that they can factor potential changes in supply for certain drugs into their patient-care decisions. The Notice to Hospitals is available on the Health Canada website: http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2011/ben_ven_nth-aah-eng.php

Recognizing drug shortages as a global issue, Health Canada has consulted with and will continue to consult with international regulatory counterparts, including the US Food and Drug Administration, the EMA and Australian Therapeutic Goods Administration, to assess the problem in other countries and the response being taken or considered.

Where can Canadians find information on drug shortages?

Canadians may view drug shortage information at the following websites:
University of Saskatchewan - Saskatchewan Drug Information Services (SDIS) (http://druginfo.usask.ca/healthcare_professional/drug_shortages.php);
Ruptures d'approvisionnement en médicaments au Canada (http://vendredipm.wordpress.com/); and
Rx&D Canada's Research Based Pharmaceutical Companies (http://www.canadapharma.org/shortage/index.asp?l=en).

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August 18, 2011

MEDIA LINES
Health Canada Notice to Hospitals re: Ben Venue Laboratories

ISSUE: Health Canada has issued a Notice to Hospitals (NtH) concerning ongoing quality concerns at Ben Venue Laboratories (BVL) located in the U.S. The NtH advises health care professionals of a potential supply shortage of certain drugs imported from BVL. *(NtH will be sent on August 17 and web-posted August 18)*

KEY MESSAGES:

- Health Canada has concerns about identified shortcomings in the Good Manufacturing Practices (GMPs) at Ben Venue Laboratories (BVL), a U.S.-based contract manufacturer.
- Many of the drugs affected by this notice are deemed "non-medically necessary", which means there are alternatives available or deal with non-life-threatening conditions.
- For drugs that are considered "medically necessary", Health Canada has a process in place to allow these drugs to continue coming into Canada, while the GMP situation is addressed. (See the Notice for a complete product list.)
- Health Canada gave medical professionals a heads up that we had concerns, so they wouldn't be caught off guard and that patients could get the care they need.

Supplementary Messages:

- The potential shortage is the result of deficiencies identified in Good Manufacturing Practices (GMPs) at BVL that may have an impact on product quality. No specific health risk has been identified at this time.
- Should Health Canada determine that there is a health risk associated with these medically necessary drugs that outweigh their benefits to Canadian patients, we will take immediate and appropriate action.

Q. What about the availability of non-medically necessary drugs?

For non-medically necessary drugs, health care professionals are advised to contact the Canadian importers of BVL products for information on drug availability and on alternate suppliers.

Health Canada does not anticipate that patients will be severely affected by potential shortages of non-medically necessary drugs, as either alternatives are readily available for these drugs or the conditions they are used to treat are not considered serious/life threatening.

Q. Why is Health Canada taking this action?

Good Manufacturing Practices are a key part of the drug safety system as they lay out how best to manufacture safe and effective products. While not all GMP violations translate into significant risk to Canadians, they are a sign of a breakdown in the manufacturing process that needs to be addressed.

When these types of violations are found, Health Canada takes the appropriate action in conjunction with manufactures and distributors so that Canadians can continue to have confidence in the products they use for themselves and their families.

This Notice to Hospitals is being issued to let health professionals know about these issues so that they can factor potential changes in supply for certain drugs into their patient-care decisions.

Q. Are BVL products being recalled?

A recall of BVL products in Canada is not being considered at this time.

Should Health Canada identify a risk to health associated with any of the drugs being imported from Ben Venue Laboratories, we will take immediate and appropriate action.

Q: Can you explain how a concern can be serious enough that you will stop some products from sold, while still allowing other products to come across the border?

No risk to health has been identified at this time for either medically necessary or non medically necessary products.

Good Manufacturing Practices (GMPs) are a key part of the drug safety system as they lay out how best to manufacture safe and effective products. While not all GMP violations translate into significant risk to Canadians, they are a sign of a breakdown in the manufacturing process that needs to be addressed. When these types of violations are found, Health Canada takes the appropriate action in conjunction with manufactures and distributors so that Canadians can continue to have confidence in the products they use for themselves and their families.

As a result, if there are concerns with manufacturing of a product, Health Canada does not generally allow its importation.

However in this instance, Health Canada has chosen to allow the continued importation of medically necessary drugs from BVL as the health benefits of these drugs outweigh the risk associated with the quality concerns. Medically necessary products are used to treat a serious or life threatening condition for which an alternative is not available or not available in sufficient quantity. The same is not true for non medically necessary products.

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MO (Aug. 18, 2011)

Comme vous le savez peut-être, encourager l'industrie à régler la question du manque d'information à jour sur les pénuries de médicaments est une priorité de Santé Canada. À cette fin, la ministre Aglukkaq a demandé à l'industrie d'établir un plan pour remédier aux pénuries de médicaments.

La ministre a récemment reçu un plan très prometteur, élaboré par l'industrie et les associations de professionnels de la santé. L'engagement de l'industrie à diffuser de l'information sur des sites Internet existants est un premier pas qui vise à augmenter la transparence d'un enjeu qui peut avoir une incidence considérable sur de nombreux Canadiens et leurs proches.

http://druginfo.usask/healthcare professional/drug shortages.php et http://vendredipm.wordpress.com

Les Canadiens pourront prendre connaissance de l'information sur les pénuries de médicaments à : http://www.canadapharma.org/shortage/index.asp?l=en

Le Ministère est ravi qu'un groupe d'intervenants variés agisse rapidement, et il s'engage à élaborer des solutions pour remédier aux pénuries de médicaments afin que les professionnels de la santé disposent des outils nécessaires pour offrir aux Canadiens des soins de qualité adaptés au patient.

Lorsque la première phase du plan sera mise en œuvre et que l'établissement d'un système national à guichet unique de surveillance et de rapport des pénuries de médicaments sera finalisé en 2012, Santé Canada continuera à encourager l'industrie et les associations de professionnels de la santé à collaborer à l'échelle du système de santé pour élaborer des pratiques exemplaires sur la prévention et la gestion des pénuries de médicaments. L'objectif vise à prévenir les pénuries de médicaments en s'attaquant à leur cause profonde.

Santé Canada a aussi créé une fiche d'information à l'intention des Canadiens, que l'on peut consulter à : (INSERT URL).

As you may know, encouraging industry to work to close the information gap on drug shortages for Canadians has been a priority of Health Canada. As such, Minister Aglukkaq asked industry to establish a plan to address drug shortages.

The Minister recently received a plan developed by industry and health care professional associations which was very encouraging. Industry's commitment to post drug shortages information on existing public websites is an important first step to increase transparency on an issue that can have a significant impact on so many Canadians and those who care for them:

http://druginfo.usask/healthcare professional/drug shortages.php; and
http://vendredipm.wordpress.com

Canadians will also be able to view drug shortage information at:
http://www.canadapharma.org/shortage/index.asp?l=en

The Department is very pleased that such a diverse group of stakeholders is acting quickly and is committed to developing solutions on drug shortages to ensure that health practitioners have the tools they need to deliver high quality and patient-focused care to Canadians.

When the first phase of the plan is fully implemented and the creation of the establishment of a national one-stop drug shortages monitoring and reporting system in 2012 is finalized, Health Canada will continue to encourage industry and health care professional associations to collaborate across the health system to develop best practice guidelines for the prevention and management of drug shortages. The goal is to help prevent drug shortages by addressing their root causes.

You will also note that Health Canada has created a Frequently Asked Questions web page for Canadians, whcih can be found here: (INSERT URL).

Fiche d'information sur les pénuries de médicaments

Comment Santé Canada collabore-t-il avec l'industrie pour pallier les pénuries de médicaments?

Inciter l'industrie à combler les lacunes dans l'information qu'elle transmet aux Canadiens au sujet des pénuries de médicaments est une priorité de Santé Canada.

En mars 2011, la ministre de la Santé a écrit aux associations de l'industrie pharmaceutique pour les inciter à coopérer avec les intervenants des secteurs pharmaceutique et de la santé dans le but d'améliorer la situation actuelle.

Il incombe aux fabricants de mieux informer les établissements et les professionnels de la santé au sujet des interruptions d'approvisionnement et de collaborer avec leurs clients.

À la fin de septembre 2011, les associations de professionnels de la santé et l'industrie ont soumis un plan très prometteur à la ministre Aglukkaq. L'industrie s'est engagée à publier l'information concernant les pénuries de médicaments sur des site Internet existants, un premier pas important vers l'amélioration de la transparence en ce qui a trait à un enjeu pouvant avoir un impact significatif sur de nombreux Canadiens et leurs proches.

Santé Canada est heureux d'informer la population que l'industrie publie maintenant de l'information concernant les pénuries sur les deux sites Internet suivants : http://druginfo.usask/healthcare professional/drug shortages.php et http://vendredipm.wordpress.com. Les Canadiens pourront aussi obtenir des renseignements sur le sujet à l'adresse suivante : http://www.canadapharma.org/shortage/index.asp?l=fr

Santé Canada encourage l'industrie et les associations de professionnels de la santé à poursuivre leur collaboration en vue d'établir un système national centralisé pour la surveillance et la déclaration des pénuries de médicaments en 2012. Santé Canada s'attend également à ce que l'industrie continue de coopérer afin d'éviter d'éventuelles pénuries de médicaments et de corriger le problème à la source.

Qu'est-ce qui cause les pénuries de médicaments?

Les pénuries de médicaments constituent un défi planétaire. Il s'agit d'interruptions temporaires de l'approvisionnement pour diverses raisons, dont :

- le retrait d'un produit par le fabricant;
- un contretemps, comme la perte d'un produit de masse durant le transport;
- l'arrêt de production par la compagnie qui doit améliorer ses processus de fabrication afin de respecter les normes de qualité;
- une pénurie mondiale des matières premières requises pour fabriquer un produit donné.

Quel est le rôle du gouvernement fédéral?

Santé Canada doit s'assurer que les produits offerts sur le marché canadien respectent des normes rigoureuses d'innocuité, d'efficacité et de qualité.

En cas de pénurie de médicaments importants, Santé Canada collabore avec les fabricants et les professionnels de la santé afin d'en atténuer les répercussions. Notre travail consiste notamment à

assurer l'accès d'urgence à des solutions de rechange, à collaborer avec les compagnies pour régler des situations problématiques concernant la fabrication et la qualité, et à accélérer le processus d'examen pour appuyer les changements dans la fabrication et les nouveaux fournisseurs.

Conscient qu'il s'agit d'un enjeu mondial, Santé Canada a consulté et consulte des organismes de réglementation d'ailleurs dans le monde, dont la Food and Drug Administration des États-Unis, afin d'évaluer l'ampleur du problème dans d'autres pays et les solutions mises en œuvre ou envisagées.

Que faire pour atténuer l'impact des pénuries et répondre aux besoins des patients?

Les médicaments sont fabriqués et distribués par l'industrie. Les fabricants sont donc les mieux placés pour comprendre les tendances de la demande et prévenir une éventuelle pénurie. Ces sites Web sont une autre façon pour l'industrie d'aviser les professionnels de la santé de toute situation pouvant mener à une pénurie.

Plus les établissements de santé sont informés rapidement d'une interruption à venir de l'approvisionnement, plus ils peuvent intervenir rapidement afin de:

- repérer des surplus de stock dans d'autres établissements;
- adopter des solutions de rechange;
- réserver les stocks restants aux personnes qui en ont le plus besoin.

Cela peut éviter l'interruption de traitements essentiels pour les patients souffrant d'une maladie grave.

Que fait l'industrie en l'occurrence?

L'industrie publie maintenant directement sur des sites Internet existants l'information concernant les pénuries de médicaments, un premier pas important vers une plus grande transparence au sujet d'un enjeu qui peut avoir une forte incidence sur de nombreux Canadiens et leurs proches.

L'information est publiée sur les deux sites suivants :
http://druginfo.usask/healthcare professional/drug shortages.php
http://vendredipm.wordpress.com.

Les Canadiens pourront aussi obtenir des renseignements sur le sujet à l'adresse suivante :
http://www.canadapharma.org/shortage/index.asp?l=fr

Pourquoi Santé Canada ne force-t-il pas les compagnies à rendre les médicaments disponibles pour répondre aux besoins des patients?

Les médicaments sont fabriqués et distribués par l'industrie. Santé Canada détient de vastes pouvoirs relatifs à la vente de médicaments au pays et s'assure qu'ils respectent des normes rigoureuses d'innocuité, d'efficacité et de qualité. Or, ces pouvoirs ne permettent pas au Ministère de forcer les compagnies à offrir un produit sur le marché canadien ou à maintenir des stocks suffisants pour répondre aux besoins des patients. Ces décisions d'affaire relèvent essentiellement de l'industrie.

Avec qui dois-je communiquer si je n'arrive pas à me procurer un médicament?

Les Canadiens affectés par une éventuelle pénurie peuvent consulter leur médecin au sujet d'une solution de rechange. Ils peuvent aussi communiquer directement avec le fabricant du produit qui est le premier informé d'une interruption possible de l'approvisionnement.

Les Canadiens peuvent aussi consulter les sites Internet ci-dessous pour savoir si un produit est menacé par une éventuelle pénurie :

http://druginfo.usask/healthcare professional/drug shortages.php
http://vendredipm.wordpress.com

Les Canadiens peuvent aussi se renseigner sur les pénuries de médicaments à l'adresse suivante :
http://www.canadapharma.org/shortage/index.asp?l=fr

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BCP (à venir)

Web info sheet on Drug Shortages

How is Health Canada working with the industry to address drug shortages?

Encouraging industry to work to close the information gap on drug shortages for Canadians has been a priority of Health Canada.

In March 2011, the Minister of Health wrote to drug product industry associations, encouraging them to work with health care and pharmacy stakeholders to find solutions to improve the current situation.

The ability to provide better information on supply disruptions to health care institutions and professionals exists within the hands of manufacturers working together with whom they supply.

At the end of September 2011, Minister Aglukkaq received a plan developed by industry and health care professional associations which was very encouraging. Industry is committed to posting drug shortages information on existing public websites. This is an important first step to increase transparency on an issue that can have a significant impact on so many Canadians and those who care for them.

Health Canada is pleased to report that industry is now directly reporting drug shortage information to two drug shortage websites: http://druginfo.usask/healthcare professional/drug shortages.php and http://vendredipm.wordpress.com. Canadians will also be able to view drug shortage information at: http://www.canadapharma.org/shortage/index.asp?l=en

Health Canada encourages industry and health care professional associations to continue to collaborate to establish a national, one-stop drug shortages monitoring and reporting system in 2012. Health Canada will also continue to look to industry to work cooperatively to prevent drug shortages by addressing their root causes.

What causes drug shortages?

Drug shortages are a global challenge. Shortages are temporary supply interruptions that can have a variety of causes. These include:

- a manufacturer removing one of their products from the market;
- a mishap, such as a mass product loss in shipping;
- a company needing to pause production to make manufacturing improvements in order to meet quality standards; and
- worldwide shortages of raw materials needed to make a certain product.

What is the Federal Government's role?

Health Canada is responsible to help ensure that products sold on the Canadian market meet high standards with respect to safety, efficacy and quality.

In circumstances where shortages of important drugs do occur, Health Canada will work with manufacturers and health professionals to minimize the impacts of drug shortages. Our work includes providing access to alternatives on an emergency basis, working with companies to resolve

manufacturing and quality issues, and expediting review to support manufacturing changes or new suppliers.

Recognizing this as a global issue, Health Canada has consulted with and will continue to consult with international regulatory counterparts, including the US Food and Drug Administration, to assess the problem in other countries and the response being taken or considered.

What should happen to lessen the impact of shortages and meet patient needs?

Drugs are manufactured and supplied by industry. As such, manufacturers are in the best position to understand the demands for their product and to anticipate any potential shortages. These websites provide another way for industry to notify health care professionals of any issues that could lead to a shortage.

The sooner health care institutions and health care practitioners are informed about a coming supply disruption, the sooner they can make arrangements to:

- locate surplus supplies held by counterparts;
- decide on alternative medication(s) available on the market; and/or
- ration existing supplies for greatest needs.

These actions can help ensure critical therapies for serious conditions are uninterrupted for patients.

What is Industry doing about drug shortages?

Industry is now directly reporting drug shortage information to two drug shortage websites:
http://druginfo.usask/healthcare professional/drug shortages.php
http://vendredipm.wordpress.com.

Canadians will also be able to view drug shortage information at:
http://www.canadapharma.org/shortage/index.asp?l=en

The posting of information on drug shortage websites is a good first step in enhancing transparency about shortages to health professionals and Canadians.

Why doesn't Health Canada force companies to make drugs available to meet patient needs?

Drug products are manufactured and supplied by industry. Health Canada has a broad authority with respect to the sale of drugs in Canada to help ensure that they meet high standards with respect to safety, efficacy and quality. This authority does not extend to forcing companies to bring a product to the Canadian market or maintaining sufficient supplies to meet the needs of patients. These are business decisions and are the responsibility of industry.

If I can't get a drug, who should I contact?

Canadians should speak to their healthcare practitioner regarding any questions or concerns about health products that may be in shortage or potential alternatives. They may also wish to directly contact the product manufacturer, who will be the first to know about potential supply disruptions.

Canadians may also wish to visit the following web sites to determine if a specific product has been identified in shortage:

http://druginfo.usask/healthcare professional/drug shortages.php and http://vendredipm.wordpress.com.

Canadians will also be able to view drug shortage information at:

http://www.canadapharma.org/shortage/index.asp?l=en

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INFOCAPSULE

Groupe de travail multi-intervenants sur les pénuries de médicaments

QUESTION : Le 29 septembre 2001, le Groupe de travail multi-intervenants sur les pénuries de médicaments a répondu à la demande de la ministre de la Santé d'élaborer un plan visant à alerter les médecins et les Canadiens de manière proactive au sujet de toute éventuelle pénurie de médicaments. Le Groupe de travail, composé de représentants de l'industrie et des associations de professionnels de la santé, a proposé de commencer par recueillir des renseignements sur les pénuries et de les publier dans deux sites Internet actifs sur les pénuries de médicaments, soit http://druginfo.usask/healthcare professional/drug shortages.php et http://vendredipm.wordpress.com. Il s'est également engagé à créer un système unique de surveillance des pénuries de médicaments.

Messages clés sur la proposition du Groupe de travail

- Santé Canada juge prioritaire d'inciter l'industrie à prendre des mesures afin de combler les lacunes en matière d'information sur les pénuries de médicaments dans l'intérêt des Canadiens.

- Santé Canada accueille favorablement les propositions du Groupe de travail, qui indiquent que toutes les parties s'entendent pour accorder la priorité à la santé des Canadiens et aux besoins des patients. Ces propositions viennent aussi confirmer que l'industrie est la mieux placée pour prévenir les médecins et les pharmaciens et leur donner ainsi suffisamment de temps pour ajuster les plans de traitement des patients.

- La publication de renseignements dans les deux sites Internet proposés est un bon premier pas en vue d'accroître la transparence relativement aux pénuries de médicaments. Il faudra aussi veiller à ce que les sites continuent d'assurer l'accès au plus grand nombre possible de renseignements précis et utiles, notamment des conseils formulés par et pour les médecins sur la manière de modifier leur pratique en fonction de la pénurie.

- La création d'un site unique donnant des renseignements complets sur les pénuries de médicaments serait le meilleur moyen de tenir les Canadiens et les médecins au courant des pénuries. Nous attendons avec impatience que le Groupe de travail présente un plan à cet égard au début de 2012.

- Plus important encore, nous continuerons aussi de compter sur l'industrie pour qu'elle travaille en collaboration dans le but de prévenir les pénuries de médicaments.

Messages généraux sur les pénuries de médicaments

- Les pénuries de médicaments constituent un défi planétaire.

- À l'échelle mondiale, les pénuries de matières premières, les difficultés de fabrication, la consolidation de la fabrication en un nombre limité de sites de production mondiaux et les changements planétaires en matière d'approvisionnement ou de demande ne sont que quelques-uns des facteurs qui influent sur l'approvisionnement. Il n'incombe pas toujours seulement à une installation, une entreprise ou un pays de résoudre un problème de pénurie.

- Les fabricants sont les premiers à être au courant des ruptures d'approvisionnement et peuvent en informer rapidement les professionnels de la santé, pour que ces derniers aient le temps d'adapter

leurs plans de traitement. En d'autres termes, l'industrie est la mieux placée pour mettre en œuvre les solutions idéales.

Questions et réponses

Q1. Qu'est-ce qui est fait à court terme pour informer le public?

R1. La publication de renseignements dans les deux sites Internet proposés est un bon premier pas en vue d'accroître la transparence relativement aux pénuries de médicaments. Il faudra aussi veiller à ce que les sites continuent d'assurer l'accès au plus grand nombre possible de renseignements précis et utiles, notamment des conseils formulés par et pour les médecins sur la manière de modifier leur pratique en fonction de la pénurie.

Q2. Quels sont les plans à long terme pour remédier au problème?

R2. La création d'un site unique donnant des renseignements complets sur les pénuries de médicaments serait le meilleur moyen de tenir les Canadiens et les médecins au courant des pénuries. Nous attendons avec impatience que le Groupe de travail présente un plan à cet égard au début de 2012.

Plus important encore, nous continuerons aussi de compter sur la collaboration de l'industrie pour prévenir les pénuries en s'attaquant aux causes profondes.

Q3. Le président Obama a ordonné à la FDA de pallier les pénuries, ce qui semble être une approche plus pratique que le site d'échange d'information qui sera créé au Canada. Pourquoi le Canada ne suit-il pas l'exemple des États-Unis?

R3. Mes collaborateurs ont pris contact avec leurs homologues américains pour discuter de la question des pénuries de médicaments. Ces discussions vont se poursuivre et nous continuerons de tirer profit de leurs expériences.

Dès que Santé Canada aura connaissance d'une pénurie importante, mes collaborateurs travailleront de concert avec les fabricants et le milieu médical et agiront dans les limites des pouvoirs du Ministère en tant qu'organisme de réglementation des médicaments dans le but de réduire l'incidence de la pénurie et de faciliter l'accès à des solutions de rechange.

MEDIA LINES

Multi-Stakeholder Working Group on drug shortages

ISSUE: On September 29, 2001 the Multi-Stakeholder Working Group on drug shortages responded to the Minister of Health's call for a plan to proactively alert physicians and Canadians about potential drug shortages. The Working Group – composed of industry and health professional associations – has proposed as a first step the collection and posting of shortage information on two currently live drug shortage web sites http://druginfo.usask/healthcare professional/drug shortages.php and http://vendredipm.wordpress.com It has also committed to the creation of a "one stop shop" drug shortages monitoring system.

Key Messages on the Working Group Proposal

- Encouraging industry to work to close the information gap on drug shortages for Canadians has been a priority of Health Canada

- Health Canada welcomes the Working Group's proposals. They show that all players have come together to put the health of Canadians and the needs of patients first They confirm that industry is best placed to proactively alert physicians and pharmacists and give them lead time to adjust treatment plans for patients.

- The posting of information on the two proposed drug shortage websites is a good first step in enhancing transparency about shortages to health professionals and Canadians. It will be important to ensure that the sites continue to help ensure that broadest possible availability of accurate and useful information such as guidance by and for practitioners on how to adapt their practice to the shortage situation.

- The creation of a one stop, comprehensive drug shortage information site would be the best way to keep Canadians and practitioners informed of shortages. And we look forward to the Working Group coming forward with a plan for such a site in early 2012.

- Most importantly, we will also continue to look to industry to work cooperatively to help prevent drug shortages.

General Messages on Drug Shortages

- Drug shortages are a global challenge.

- Worldwide shortages of raw materials, manufacturing difficulties, the consolidation of manufacturing into a limited number of global production sites, and global changes in supply or demand are just some of the factors that can affect supply. The ability to resolve a shortage doesn't always rest with one facility, one company or one country.

- Manufacturers know first of supply disruptions and can inform health system professionals fastest, providing lead time to adjust treatment plans. Simply put, industry is best placed to implement ideal solutions.

Questions and Answers

Q1. In the short term, what is being done to inform the public?

A1. The posting of information on the two proposed drug shortage websites is a good first step in enhancing transparency about shortages to health professionals and Canadians. It will be important to ensure that the sites continue to develop to ensure that broadest possible availability of accurate and useful information such as guidance by and for practitioners on how to adapt their practice to the shortage situation.

Q2. What are the long term plans to address the problem?

A2. The creation of a one stop, comprehensive drug shortage information site would be the best way to keep Canadians and practitioners informed of shortages. And we look forward to the Working Group coming forward with a plan for such a site in early 2012.

Most importantly, we will also continue to look to industry to work cooperatively to prevent drug shortages by addressing their root causes.

Q3. President Obama has ordered the FDA to deal with shortages; which appears to be more hands on than the info-sharing website that will be developed in Canada. Why isn't Canada taking a similar approach?

A3. My officials have been in touch with their international counterparts in the US to discuss the issue of drug shortages. We will continue to have these discussions and to draw on their experiences.

When Health Canada becomes aware of a significant shortage, my officials will work with manufacturers and the medical community, and acts within our powers as the drug regulator to reduce the impact of the shortage and facilitate access to alternatives

Fw: For MO approval: Web posting for Drug shortages
Blossom Leung to: Alexis M Tervo 2011-11-21 09:19 AM
Cc: erin.junker

Hi Alexis,

Any word on MO approval for this? If we are to meet the COB Monday deadline, I will need this back ASAP for the web team.

Thanks,
Blossom

Blossom Leung
Communications Coordinator / Coordonnatrice des communications
Public Affairs, Consultation and Communications Branch /
Direction générale des affaires publiques, de la consultation et des communications
Health Canada / Santé Canada
Tel/Tél: (613) 957-2974
Cell/Portable: (613) 552-4118
Fax/Téléc: (613) 957-1729
blossom.leung@hc-sc.gc.ca
----- Forwarded by Blossom Leung/HC-SC/GC/CA on 2011-11-21 09:18 AM -----

From:	Blossom Leung/HC-SC/GC/CA
To:	Alexis M Tervo/HC-SC/GC/CA@HWC
Cc:	erin.junker@hc-sc.gc.ca, Charles Mojsej/HC-SC/GC/CA@HWC
Date:	2011-11-18 02:18 PM
Subject:	For MO approval: Web posting for Drug shortages

Hi Alexis,

Please find attached, for MO approval, the web posting on drug shortages, as requested by MO.

As you know, Steve requested that this be posted by COB Monday. In order to meet these deadlines, I'll require MO approval ASAP.

As well, could you let us know whether MO would like the letters from the Minister to the drug companies posted to the web?

ISSUE STATEMENT: On November XX, 2011, Health Canada will web post an information sheet on the issue of drug shortages. The Minister's letter to industry and their response back to the Minister may also be webposted (TBC).

HPFB_Web_Drug Shortages_Nov18_1416.doc

Thanks,
Blossom

Blossom Leung
Communications Coordinator / Coordonnatrice des communications
Public Affairs, Consultation and Communications Branch /
Direction générale des affaires publiques, de la consultation et des communications
Health Canada / Santé Canada
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blossom.leung@hc-sc.gc.ca

Web info sheet on Drug Shortages

What causes drug shortages?

Drug shortages are a global challenge. Shortages are temporary supply interruptions that can have a variety of causes. These include:

- a manufacturer removing one of their products from the market;
- a mishap, such as a mass product loss in shipping;
- a company needing to pause production to make manufacturing improvements in order to meet quality standards; and
- worldwide shortages of raw materials needed to make a certain product.

What should happen to lessen the impact of shortages and meet patient needs?

Drugs are manufactured and supplied by industry. As such, manufacturers are in the best position to understand the demands for their product and to anticipate any potential shortages. Health Canada encourages companies to provide notification to health care professionals for any issues that could lead to a shortage.

The sooner health care institutions and health care practitioners are informed about a coming supply disruption, the sooner they can make arrangements to:

- locate surplus supplies held by counterparts;
- decide on alternative medication(s) available on the market; and/or
- ration existing supplies for greatest needs.

These actions can help ensure critical therapies for serious conditions are uninterrupted for patients.

What is the Federal Government's role?

Health Canada is responsible to help ensure that products sold on the Canadian market meet high standards with respect to safety, efficacy and quality.

In circumstances where shortages of important drugs do occur, Health Canada will work with manufacturers and health professionals to minimize the impacts of drug shortages. Our work includes providing access to alternatives on an emergency basis, working with companies to resolve manufacturing and quality issues, and expediting review to support manufacturing changes or new suppliers.

Recognizing this as a global issue, Health Canada has consulted with and will continue to consult with international regulatory counterparts, including the US Food and Drug Administration, to assess the problem in other countries and the response being taken or considered.

What is Industry doing about drug shortages?

Industry has committed to posting drug shortages information on existing public websites. This is an important first step for increased transparency on an issue that can have a significant impact on so many Canadians and those who care for them.

The posting of information on the two proposed drug shortage websites is a good first step in enhancing transparency about shortages to health professionals and Canadians.

Canadians and health care practitioners can visit the following web sites to determine if a specific product has been identified to be in shortage:

http://druginfo.usask/healthcare professional/drug shortages.php and
http://vendredipm.wordpress.com.

Canadians will also be able to view drug shortage information at:

http://www.canadapharma.org/shortage/index.asp?l=en

Why doesn't Health Canada force companies to make drugs available to meet patient needs?

Drug products are manufactured and supplied by industry. Health Canada has a broad authority with respect to the sale of drugs in Canada to help ensure that they meet high standards with respect to safety, efficacy and quality. This authority does not extend to forcing companies to bring a product to the Canadian market or maintaining sufficient supplies to meet the needs of patients. These are business decisions and are the responsibility of industry.

How is Health Canada working with the industry to address drug shortages?

Encouraging industry to work to close the information gap on drug shortages for Canadians has been a priority of Health Canada.

In March 2011, the Minister of Health wrote to drug product industry associations, encouraging cooperation with health care and pharmacy stakeholders to take a collaborative approach to improving the current situation.

The ability to provide better information on supply disruptions to health care institutions and professionals exists within the hands of manufacturers working together with whom they supply.

Most importantly, Health Canada will continue to work cooperatively with Industry to prevent drug shortages by addressing their root causes.

If I can't get a drug, who should I contact?

Canadians should speak to their healthcare practitioner regarding any questions or concerns about health products that may be in shortage or potential alternatives. They may also wish to directly contact the product manufacturer, who will be the first to know about potential supply disruptions.

Canadians may also wish to visit the following web sites to determine if a specific product has been identified in shortage:

http://druginfo.usask/healthcare professional/drug shortages.php and
http://vendredipm.wordpress.com.

Canadians will also be able to view drug shortage information at:

http://www.canadapharma.org/shortage/index.asp?l=en

If my medication is not available in Canada and I want to import a drug from another country, who should I contact?

Canadians may wish to speak to their healthcare practitioner regarding Health Canada's Special Access Programme. This programme provides access to non-marketed drugs for practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or unavailable. Requests for access to a drug through the SAP are initiated by a physician, and if authorized, permit a manufacturer to sell a drug that cannot otherwise be sold or distributed in Canada.

Prepared by:
Aldège Bellefeuille, Communications
Reviewed by: Joanne Garrah, PPIAD

Approved by:
Kendal Weber, DG, PPIAD, (November 17, 2011)
Nancy Othmer, Legal Services, (November 18, 2011)
David Gotlieb for Ken Polk, Communications Executive, (November 18, 2011)
Sophie Galarneau, Director, Public Affairs (pending)
Paul Glover, ADM, HPFB (pending)
Anne Lamar, ADM, PACCB (pending)
DMO, (pending)
MO, (pending)
PCO, (pending)

Health Canada / Santé Canada

Approval Slip / Bordereau d'approbation

Docket Number 11-123383 - 460

For Meeting Minister	For Departmental Secretariat use only / À l'usage du Secrétariat du ministère
DEC 0 8 2011	
Prepared by / Préparé par D KW Lee / R. Yazdani Telephone/Téléphone 957-0732 / 946-1821	Ministerial Briefing Unit _____ Unité d'information ministérielle
Verified by / Vérifié par Gavin Brown Telephone/Téléphone 957-8994 Date:	
Director General / Directeur général M. Saulnier Telephone/Téléphone 960-9712 Date:	Senior Advisor _____ Conseiller(ère) principal(e)

Consultation **Signature** ***(as required / au besoin)***

Health portfolio ***(Including: Branches, Regions, Agencies, Legal)***
Portefeuille de santé ***(Compri : Directions générales, régions, agences, Services juridiques)***

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Other Government Departments
Exigence d'autres ministères

_____	_____ *name printed and signature / nom imprimé et signature*

Final Approval

Signature of Branch/Agency Head Signature du responsable de la DG/Agence	Branch/Agency Acronyme de la DG/Agence	Date

Memo to Minister for a meeting with CMA, Monday, Dec. 12/11 at 3:15 PM @ 458 Confederation Bldg.
Speaking Notes included.

Copied to
Liste de diffusion

M:\Health Care System (HCS)\Action Requests\Min\2011\11-123383-460 - Min meeting with CMA\:
Memo_MIN_CMA.wpd
Appendix A_Health Accord.wpd
Appendix B_Medical Marihuana.wpd
Appendix C_Drug Shortages.wpd
Appendix D_Bio_Dr John Haggie.wpd

FOR A MEETING

11-123383 - 460

MEMORANDUM TO THE MINISTER OF HEALTH

Meeting with the President of the Canadian Medical Association (CMA)
458 Confederation Building,
Monday, December 12, 2011, 3:15 PM

KEY MESSAGES

- The November 24-25, 2011, meeting of F/P/T Health Ministers discussed what had been accomplished since 2004 and considered the challenges and priorities on moving forward.
- The federal government is interested in hearing more about the CMA's activities and how the CMA is engaging its members in making the health system more sustainable while improving accountability.
- The CMA has also raised concerns about proposed changes to the Medical Marihuana Access Program and is working with other health stakeholders to increase transparency regarding drug shortages.

BACKGROUND:

This meeting with the President of the Canadian Medical Association, Dr. John Haggie, will discuss three topics: current status of discussions on a future Health Accord; Marihuana Medical Access Regulations; and Drug Shortages.

Details of these three topics are included as Appendices A to C. Biographical details of Dr. Haggie are included as Appendix D.

.../2

The CMA is the national advocacy body for physicians in Canada. The CMA's mission is to serve and unite the physicians of Canada and be the national advocate, in partnership with Canadians, for the highest standards of health and health care. The CMA is a voluntary professional organization representing nearly 75,000 physicians and comprising twelve provincial and territorial medical associations and 51 national medical organizations.

CURRENT STATUS:

Health Accord

The CMA has been particularly engaged on Accord renewal, as it sees it as an opportunity to transform the health system. This has been a specific policy focus of the organization over the last few years, with the CMA developing a framework and policy paper, including six principles to guide health system transformation (health care should be **patient-centred** and focus on **quality**; focus needed on population health through **health promotion and illness prevention** and **equitable access to care**; health system needs to be **sustainable** and **accountable**). The CMA has also conducted a national dialogue on health care transformation through town halls and its website.

Interest in Accord renewal by the CMA has now sharpened further to the HMM discussion and with the ongoing Senate review of the 2004 Health Accord. Dr. Haggie appeared before the Senate hearing on October 19 and December 2, 2011 to discuss his views on the 2004 Accord and his opinions for Accord renewal. At those meetings, he noted the importance of focussing on three key strategies for Accord renewal: quality, innovation and accountability. He also supported the need for national principles that would provide pan-Canadian standards for health care while providing jurisdictions flexibility to accommodate regional priorities.

Marihuana Medical Access Regulations

The CMA has expressed significant concerns with the proposed changes to the Medical Marihuana Access Program, particularly due to the fact that medical practitioners would play a role in supporting the use of an unproven therapeutic product.

.../3

Drug Shortages

The CMA is a member of a multi-stakeholder group which is collaborating on the issue of drug shortages, including discussing options for providing notification of shortages to key stakeholders. The working group has developed a two-phase plan for improving transparency around drug shortages.

PORTFOLIO CONSIDERATIONS:

The Healthy Environments and Consumer Safety Branch was consulted on the Marihuana Medical Access Regulations and the Health Products and Food Branch provided input on Drug Shortages.

NEXT STEPS:

The Health Care Strategies Directorate of the Strategic Policy Branch will coordinate any follow up required after the meeting.

Deputy Minister's Office

MECS # 11-123383 - 460

Branch Head: Abby Hoffman
Telephone: 613-946-1791

Attachments:
Appendix A – Health Accord
Appendix B – Marihuana Medical Access Regulations
Appendix C – Drug Shortages
Appendix D – Biographical details of Dr. John Haggie

Document created on:
December 9, 2011

HECSB INPUT FOR TALKING POINTS - HECSB ADM APPROVED

MINISTER'S OFFICE REQUEST

ISSUE:

The Minister is meeting with the Canadian Medical Assocation (CMA) on Monday, December 12, to discuss the reform of the Marihuana Medical Access Program.

On September 29, 2011, Health Canada officials met with representatives of the CMA to discuss the proposed reforms. The CMA expressed significant concerns with the proposal, particularly due to the fact that medical practitioners would play a role in supporting the use of an unproven therapeutic product.

TALKING POINTS:

Reform of Marihuana Medical Access Program

- The Government of Canada has a constitutional obligaton to provide reasonable access to a legal source of marihuana for medical purposes. That is why the Marihuana Medical Access Program was put in place in 2001.
- However, we are very concerned that the current Program is open to abuse and exploitation by criminal elements. That is why we are proposing changes to the program.
- These changes reflect concerns that we have heard from groups such as municipal governments, as well as law enforcement, fire officials, program participants and the medical profession.
- I understand that during consultations with my officials on the proposed changes, representatives of your Association expressed concerns related to the role of medical practitioners in supporting the use of marihuana for medical purposes, particularly since this is an unproven therapeutic product.
- Your representatives also discussed the need for more information to be made available to medical practitioners if they are expected to play this role.
- Let me assure you that I understand your concerns.

- I would like to reiterate that Health Canada believes that medical practitioners are the best placed individuals to make determinations regarding treatment of patient illnesses.
- Marihuana remains one treatment option among many. Under a reformed program, the determination as to whether or not it is appropriate for a patient will remain with the medical practitioner, and there is not requirement that a physician support the use of marihuana if they do not deem it appropriate.
- We have heard from many individual physicians that they would like to receive more information information about marihuana in order to be able to make this determination on a case-by-case basis. That is why we are putting in place an Expert Advisory Committee as a fundamental component of this reform.
- The role of this committee will be to provide accurate, comprehensive and up-to-date information on the use of marihuana for medical purposes, and to assist Health Canada in determining how best to present this information in a way that is useful to physicians.
- Understanding the needs of physicians is key. That is why I have also asked my officials to work closely with the medical community as we move forward with this reform. They are finalizing the development of a needs assessment survey, which was piloted at the Family Medicine Forum in November.
- It would be useful to us if your Association could assist in the dissemination of such a needs survey. With your assistance, I am confident that this will reach enough medical practitioners to be able to gain valuable information regarding the needs of physicians.
- I hope that we can all agree that the proposed reforms will address significant public health and safety concerns that will benefit Canadians, and I trust that I will be able to count on the support of the CMA and its membership as we move forward.
- My officials will continue to engage the CMA as the Department progresses with the reform of this program.

If pressed on the role of other health care professionals:

- Health Canada is engaging with the provinces and territories on the potential role of other health care professionals, such as nurse practitioners and pharmacists.

If pressed on research:

- The Government of Canada believes that clinical research on the use of marihuana for therapeutic purposes and the development of marihuana based products is best undertaken by the private sector, such as pharmaceutical companies.

If pressed on legalization:

- Marihuana is a controlled substance in Canada under the Controlled Drugs and Substances Act. Legalization or decriminalization of marihuana is not part of these changes.

Deputy Minister's Office

MECS # 11-120254-837

Branch Head: Abby Hoffman

Telephone: 946-1791

s.21(1)(b)
s.21(1)(c)

APPENDIX A

HEALTH ACCORD

Health Accord Negotiations

The *Ten Year Plan to Strengthen Health Care* (the 2004 Health Accord) is set to conclude in 2014. The Accord included commitments related to wait times reduction, primary health care reform, health human resources, home care, a National Pharmaceuticals Strategy, access to care in the North, health innovation, public health, accountability commitments and dispute avoidance and resolution. Aboriginal health and Quebec asymmetrical federalism were addressed in separate communiqués.

Cash levels for the Canada Health Transfer (federal funding for health care) tied to the 2004 Health Accord are set in federal legislation up to 2013-2014. The November 8, 2011 *Update on Economic and Fiscal Projections* confirmed the extension of the 6% escalator through 2015-16. Projected transfer growth rates beyond then will be finalized in the context of transfer renewal.

In June 2011 Speech from the Throne, the Government of Canada committed to maintaining the 6% escalator while working collaboratively with the provinces and territories (P/Ts) to renew the Health Accord and continue reducing wait times. It also committed to working with P/Ts to ensure that the health care system is sustainable and that there is accountability for results.

On November 24-25, 2011, Health Ministers met to discuss a number of issues, including lessons learned from the 2004 Health Accord and the challenges and priorities for moving forward.

Considerations

There has been considerable stakeholder interest in Accord renewal over the last few years, as many see it is as an opportunity to put in place transformative measures to modernize the health care system. The CMA has been particularly engaged on this issue. Its main policy focus in recent years has been on health system transformation.

Speaking Points

- On November 24-25, 2011, I met with my provincial and territorial counterparts to discuss what has been accomplished since 2004 and to consider challenges and priorities for moving forward.

- The discussion touched on many of the principles you have proposed. In particular, we talked about improving accountability, which is a priority for this Government.

- All jurisdictions have started paying more attention to measuring health system performance. While there is still work to be done, I am encouraged to see that we can now compare wait times across the country for key procedures.

- It would be helpful if we could build on those successes. Federally, we support further work on common indicators.

- I am encouraged to see that several provinces have begun expanding their performance measurement to other types of services, like emergency room waits. Most provinces now have quality councils, which play an important role in driving improved health care performance.

- Physicians also have an important role to play in improving accountability and the system more generally. I am interested in hearing more about your activities and how the CMA is engaging its members in making the health system more sustainable while improving accountability and demonstrating results to Canadians.

APPENDIX B

MARIHUANA MEDICAL ACCESS REGULATIONS

Background

On September 29, 2011, Health Canada officials met with representatives of the CMA to discuss the proposed reforms. The CMA expressed significant concerns with the proposal, particularly due to the fact that medical practitioners would play a role in supporting the use of an unproven therapeutic product.

Speaking Points

Reform of Marihuana Medical Access Program

- The Government of Canada has a constitutional obligation to provide reasonable access to a legal source of marihuana for medical purposes. That is why the Marihuana Medical Access Program was put in place in 2001.
- However, we are very concerned that the current Program is open to abuse and exploitation by criminal elements. That is why we are proposing changes to the program.
- These changes reflect concerns that we have heard from groups such as municipal governments, as well as law enforcement, fire officials, program participants and the medical profession.
- I understand that during consultations with my officials on the proposed changes, representatives of your Association expressed concerns related to the role of medical practitioners in supporting the use of marihuana for medical purposes, particularly since this is an unproven therapeutic product.
- Your representatives also discussed the need for more information to be made available to medical practitioners if they are expected to play this role.
- Let me assure you that I understand your concerns.
- I would like to reiterate that Health Canada believes that medical practitioners are the best placed individuals to make determinations regarding treatment of patient illnesses.
- Marihuana remains one treatment option among many. Under a reformed program, the determination as to whether or not it is appropriate for a patient will remain

with the medical practitioner. There will not be a requirement that a physician support the use of marihuana if they do not deem it appropriate.

- We have heard from many individual physicians that they would like to receive more information about marihuana in order to be able to make this determination on a case-by-case basis. That is why we are putting in place an Expert Advisory Committee as a fundamental component of this reform.
- The role of this committee will be to provide accurate, comprehensive and up-to-date information on the use of marihuana for medical purposes, and to assist Health Canada in determining how best to present this information in a way that is useful to physicians.
- Understanding the needs of physicians is key. That is why I have also asked my officials to work closely with the medical community as we move forward with this reform. They are finalizing the development of a needs assessment survey, which was piloted at the Family Medicine Forum in November.
- It would be useful to us if your Association could assist in the dissemination of such a needs survey. With your assistance, I am confident that this will reach enough medical practitioners to be able to gain valuable information regarding the needs of physicians.
- I hope that we can all agree that the proposed reforms will address significant public health and safety concerns that will benefit Canadians, and I trust that I will be able to count on the support of the CMA and its membership as we move forward.
- My officials will continue to engage the CMA as the Department progresses with the reform of this program.

If pressed on the role of other health care professionals:

- Health Canada is engaging with the provinces and territories on the potential role of other health care professionals, such as nurse practitioners and pharmacists.

If pressed on research:

- The Government of Canada believes that clinical research on the use of marihuana for therapeutic purposes and the development of marihuana based products is best undertaken by the private sector, such as pharmaceutical companies.

If pressed on legalization:

- Marihuana is a controlled substance in Canada under the Controlled Drugs and Substances Act. Legalization or decriminalization of marihuana is not part of these changes.

APPENDIX C

DRUG SHORTAGES

The production and supply process for health products is complex and on occasion, can result in supply interruptions. These can arise from a variety of different causes including manufacturing issues, shortages in raw materials, natural disasters and regulatory decisions related to the safety, efficacy or quality of a product.

As a regulator, Health Canada is responsible for reviewing the safety, quality and efficacy of drugs and for authorizing their sale in Canada. The Department is also responsible for verifying that products sold on the Canadian market continue to meet high standards with respect to safety, efficacy and quality. There are currently no regulatory requirements related to shortage prevention, supply management, shortage notification or communication.

Recent Activities

Industry Plan

On March 11, 2011 the Minister of Health sent a letter to industry associations requesting that pharmaceutical companies voluntarily provide information on drug shortages. On May 10, 2011, the Minister received a response from the Canadian Generic Pharmaceutical Association (CGPA) indicating a multi-stakeholder working group had been convened to collaborate on the issue of drug shortages, including discussing options for providing notification of shortages to key stakeholders.

The working group includes representatives from CGPA, Rx&D, and BIOTECanada, and the health professional associations (CMA, Canadian Pharmacists Association, Canadian Public Health Association).

On August 17, the Minister wrote to this multi-stakeholder group acknowledging their work with stakeholders, and asked that a plan for notification of drug shortages be submitted by September 30, 2011.

On September 28, industry along with key health care professional stakeholders, wrote back to the Minister of Health with a plan for improving transparency around drug shortages. The plan has a two-phase approach:

- In the short-term, the industry associations will provide notification of drug shortages through two existing drug shortages web sites - The Saskatchewan Drug Information Service and the Vendredi PM. The websites that host the information

will be promoted and communicated by the health professional associations to their membership and the broader community.

- Over the longer term, Industry will be exploring the development of a national one-stop drug shortages monitoring system. They will have a more detailed plan by early 2012.

On October 7, 2011, the Minister responded to the Working Group indicating their plan is an important first step for increased transparency around drug shortages. She encouraged them to continue to:

- collaborate on a plan for the establishment of a national, one-stop drug shortages monitoring and reporting system; and
- consider measures beyond information sharing, in order to create stability in their supply chains and prevent drug shortages from occurring.

Speaking Points

- Health Canada would like to acknowledge the dedication and contribution of CMA on the drug shortages working group.

- Drug shortages are not unique to a specific country but a global challenge to all health regulators.

- Encouraging industry to work to close the information gap on drug shortages for Canadians has been a priority of Health Canada.

- The ability to provide better information on supply disruptions to health care institutions and professionals exists within the hands of manufacturers working together with whom they supply.

- The plan developed by industry and health care professional associations working group is an important first step to increase transparency on an issue that can have a significant impact on so many Canadians and those who care for them.

- Given the complex, global issue of drug shortages, Health Canada has posted a web fact sheet that will provide Canadians and stakeholders with pertinent drug shortage information, including web sites that identify which medications are currently in shortage.

- More work needs to be done and will be done regarding drug shortages, but Canadians can be confident that all players have come together to put the health and the needs of patients first.

APPENDIX D

BIOGRAPHICAL DETAILS OF
DR. JOHN HAGGIE
PRESIDENT, CANADIAN MEDICAL ASSOCIATION

Dr. John Haggie is the President of the Canadian Medical Association (CMA) for 2011-2. He is a general and vascular surgeon from Gander, Newfoundland and Labrador.

Born in England, Dr. John Haggie completed his medical studies in Manchester in General Surgery. He held several positions as physician, surgeon, tutor and registrar in the North West region of England.

Dr. Haggie moved in St. Anthony, NL, in 1993 where he became consulting surgeon for the Grenfell Region Health Services. In 1997, Dr. Haggie moved to Appleton, NL, where he was appointed attending surgeon, General and Vascular Surgery at the James Paton Memorial Hospital (JPMH) in Gander, NL. He held this position until 2008 when he became chief of staff of the same hospital and he continues to serve in this capacity.

Dr. Haggie served as president of the Newfoundland and Labrador Medical Association (NLMA) in 2002. He also represented the NLMA on the CMA Board of Directors and other committees. Most recently, Dr. Haggie served on the CMA's Committee on Education and Professional Development, representing the Atlantic provinces. He also chaired the CMA's Ad Hoc Working group on Pharmaceutical issues.

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David K.W. Lee

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